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TEMEPHOS: O,O'-(thiodi-4,1-phenylene) bis(O,O-dimethyl phosphorothioate) Pesticide Registration Standard

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EPA

Temephos

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Pesticide Registration Standard

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TEMEPHOS

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TABLE OF CONTENTS

Pages

I. How to Register Under a Registration Standard.......... 1

- A. Organization of the Standard.................... 1
- B. Purpose of the Standard.......................... 1
- C. Requirements to Reregister Under the Standard.... 3
- D. "Product-Specific" Data and "Generic" Data....... 3
- E. Data Compensation Requirements Under FIFRA 3(c)(1)(D)................................ 5
- F. Obtaining Data to Fill Data Gaps; FIFRA 3(c)(2)(B)................................ 6
- G. Amendments to the Standard....................... 7

II. Regulatory Position...................................... 9

- A. Introduction..................................... 9
- B. Description of Chemical.......................... 9
- C. Regulatory Position.............................. 9
- D. Regulatory Rationale............................. 9
- E. Criteria for Registration Under the Standard..... 11
- F. Tolerance Reassessment........................... 22

III. Summary of Data Requirements and Data Gaps........... 24

- A. Table III.A Generic Data Requirements......... 25
- B. Table III.B Product-Specific Data Requirements for Manufacturing-Use Products..... 25
- C. Table III.C Product-Specific Data Requirements for End-Use Products.............. 26

IV. Product Chemistry... 55

- A. Introduction..................................... 55
- B. Chemical Identity................................ 55
- C. Manufacturing Process............................ 55
- D. Product Analytical Methods and Data.............. 57
- E. Physical/Chemical Properties..................... 57
- F. Summary of Data Gaps............................. 59

V. Environmental Fate... 60

- A. Use Summary...................................... 60
- B. Environmental Fate Profile....................... 60
- C. Exposure Profile................................. 63
- D. Summary of Data Gaps............................. 65

VI. Toxicology.. 66

- A. Toxicology Profile: Technical Temephos........... 66
- B. Toxicology Profile: Manufacturing-Use Temephos... 67
- C. Toxicology Profile: End-Use Temephos............. 68
- D. Human Hazard Assessment.......................... 70
- E. Summary of Data Gaps............................. 71

VII. Residue Chemistry 73

- A. Introduction 73
- B. Metabolism of Temephos in Plants 73
- C. Metabolism of Temephos in Animals 75
- D. Analytical Methods 75
- E. Residue in Plants 79
- F. Storage/Stability 80
- G. Residue of Temephos in Animals 80
- H. Summary of Data Gaps 81

VIII. Ecological Effects 83

- A. Ecological Effects Profile 83
- B. Hazard Assessment 84
- C. Summary of Data Gaps 85

IX. Efficacy 86

- A. Efficacy Profile 86
- B. Factors Influencing Efficacy 86
- C. Use Sites 86
- D. Summary of Data Gaps 88

X. Confidential Annex 89

XI. Bibliography 90

- A. Guide to Use of Bibliography 90
- B. Section 1: Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard
- C. Section 2: Citations Judged to be Inappropriate for Use in Developing this Standard
- D. Section 3: Standard Reference Material

I. How to Register Under a Registration Standard

A. Organization of the Standard

The first part of this document explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second part presents the Agency's regulatory position and rationale. The third part sets forth the requirements, in tabular form, that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining parts, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receiveand (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, the Environmental Protection Agency (EPA) and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product-by-product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product-by-product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978) and in 1980 (45 FR 72948, November 3, 1980), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [see FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product-by-product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have; compliance with standards of toxicity, composition, labeling, and packaging; and satisfaction of the compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expresslydesigned label precautions are strictly followed. Thus, the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use", or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use". If the Standard does classify a pesticide for "restricted use", this determination is stated in Part II of this Standard.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product-Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, Ecological Effects, and Efficacy. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 22, 1978), and in 1980 (45 FR 72948, November 3, 1980), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement were actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases, studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which the Agency has found needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product use categories (see Part III).

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1) data that are "product-specific" i.e., data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2) "generic" data that pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use.

The Agency requires certain "product-specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product-specific" data on any product other than the applicant's are irrelevant, unless the other product is similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, the Standard indicates which guideline requirement that support similar products.) "Product-specific" data on the efficacy of particular end-use products are also required where the formulation may affect public health or where failure of efficacy could cause public health problems (see 44 FR 27932, May 11, 1979).

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert" ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient e.g., the acute LD_{50} of the active ingredient in its technical or purest grade (see proposed 40 CFR 163.81-1(a), 43 FR 37355).

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food crop pesticide. However, if an end-use product's label specified that it was for use only in ways that did not involve a food/feed exposure and did not involve repeated human exposure via the oral route, then the subchronic oral study would not be relevant to the evaluation of the manufacturing-use product.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation under FIFRA Section 3(c)(1)(D) or data generation under Section 3(c)(2)(B) for "generic" data that are required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his products. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements Under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. Compensation must be offered for all data which are described by all the following criteria:

1) the data were first submitted to EPA or to its predecessor agency, USDA, or FDA on or after January 1, 1970;

2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit or a tolerance, an amendment adding a new use to a registration, or for reregistration, or to support or maintain in effect an existing registration;

3) the data are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product composition and intended use pattern(s);

4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the study to offer to pay compensation. (This exemption applies to the "generic" product, not to "product-specific" data. The exemption is available only to an applicant whose end-use product is formulated from another registered manufacturing-use product containing that active ingredient.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product-specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where, because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product-specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(c)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements. This is with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill Data Gaps; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have not been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registration oriented decisions) and have not been located in the published literature search that EPA conducted in preparation of this Standard. Such instances of missing but required data are referred to in this Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies, to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a Section 3(c)(2)(B) order, his product registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in Part III, the "generic" data gaps and "product-specific" data gaps for manufacturing- and end-use products. It also notes the classes of products to which these data gaps pertain. The Standard also points out that to be registered under the Standard, a product must be supported by certain required "product-specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product-specific" data gaps on a "product-by-product" basis. (Although the Standard will, in some cases, note which data EPA does possess that would suffice to satisfy certain "product-specific" data requirements for a category of products with similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue FIFRA Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps whether those data in question are "product-specific" or "generic" data gaps. The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

In addition, FIFRA Section 6(a)(2) requires the registrant to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. The registrant should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the Part II.C. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies may be requested from the Agency. When all of the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and reissued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identifiedinert ingredients of concern in a specific product to which the Standard applies, these ingredients will be indicated in the Guidance Package.

II. Regulatory Position

A. Introduction

This part presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing temephos as the sole active ingredient with the same use patterns described in this Standard. After briefly describing the chemical, this part presents the regulatory position and rationale, the criteria by which applicants for registration of temephos products will be approved, labeling considerations and requirements related to the tolerance reassessment, if applicable. A summary of the data requirements is contained in Part III. Discussion of the data upon which this regulatory position is based is presented in each of the disciplinary chapters, Parts IV through IX.

B. Description of Chemical

Temephos (O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl phosphorothioate) is used primarily as a mosquito larvicide. An alternative chemical name for the compound is O,O,O',O'-tetramethyl O,O'-thiodi-*p*-phenylene phosphorothioate. Temephos is also known by the trade names "Abate®", "Abathion®", "Abat®", and "Biothion®." The Chemical Abstracts Registry (CAS) number for temephos is 3383-96-8 and the EPA Shaughnessy number is 059001.

C. Regulatory Position

Temephos, as described in this Standard, may be registered for sale, distribution, reformulation and use in the United States. The Agency has considered the limited amount of scientific data obtained from the open literature as of August, 1981, and the data submitted to the Agency by the registrants through the time of publication of this Standard. Based on review of these limited data, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR) was met or exceeded for temephos and that temephos does not appear to cause unreasonable adverse effects when applied in accordance with proper label directions and precautions. Temephos products currently registered may be reregistered subject to the conditions imposed for data requirements. New products may be registered under this Standard and are subject to the same requirements. Revised label requirements will be addressed in the Guidance Package which accompanies this Standard and in Part II.E of this Standard (see 40 CFR 162.10 for a detailed description of standard labeling requirements).

D. Regulatory Rationale

A review of the available data regarding the manufacturing-use and end-use products of temephos shows that much information that could be used to support registration and reregistration is not available. The Agency has the prerogative to not only request information to satisfy the data Guidelines proposed in

1978 and 1980, but may also require additional testing. These additional tests may be requested by the Agency if it believes that particular concerns regarding the health or environmental effects of a pesticide must be evaluated. In some cases, this additional testing may be deferred pending the Agency's development of specific test protocols or the completion of other related tests (e.g., tiered testing).

It is the policy of the Agency not to automatically request guideline information just because a particular guideline exists. Each element of the guideline is considered individually with regard to the pesticide's uses, exposure and risk. If the Agency concludes that specific elements of the data guidelines are required to prepare a comprehensive Registration Standard, the data will be requested.

The Agency has concluded that it should continue registration for this product for the following reasons:

1) No significant adverse effects have been uncovered in the review of studies pertinent to temephos. These studies include some which meet guideline data requirements and some which, while failing to meet guideline requirements, provide a level of qualitative information. As a result of examining these studies, the Agency has concluded that there is no immediate cause for regulatory concern.

2) There is evidence that technical grade temephos causes only a low level of acute oral and dermal health effects. The potential for eye irritation is minimal and no adverse effects have been identified from analysis of the chronic feeding study. Furthermore, the results of one study evaluating the oncogenicity of temephos are negative.

3) The Pesticide Incident Monitoring System's Report #125 of February 1979, reports only three accidents with temephos. In one instance, 20 cattle died in a field sprayed with temephos at twice the maximum registered rate. Investigation did not produce sufficient evidence to link the registered use of the pesticide to the incident. In the second event, damaged containers of temephos contaminated the interior of a truck/trailer carrying the pesticide. In the third incident, a drum of temephos exploded and burned while being heated with a heating strap during the manufacturing of end-use products. In all these incidents there is no record of human injury or deleterious effects to the human system that could be attributed to the health and environmental effects of temephos, or effects to animals other than by misuse.

   Of these three events, none involve the pesticidal nature of temephos and the level of accidents reported involving the registered temephos use patterns are generally very low. However, due to the use of temephos in isolated aquatic areas, the Agency realizes that the incidence of accidents may not be indicative of potential hazard.

4) Based on 1976 data, it is estimated that the total number of ground applicators potentially exposed to temephos approximates less than 500; the number of applicators, mixers, loaders and flaggers potentially exposed as a result of aerial application also is less than 500*. The majority of temephos used in mosquito abatement programs is applied aerially as emulsifiable concentrate or as granular formulations. During aerial application, the pilot is usually not exposed to the spray or granules, the aircraft cockpits are usually sealed and are ventilated with a positive air flow system, and the pesticide delivery system is closed. Consequently, the number of persons potentially exposed to temephos during the application process is minimal, especially during aerial application where the potential for human exposure appears slight. Exposure to the general population is also considered minimal because temephos is used primarily in marshlands, swamps and tidal areas where human population density is generally low.

5) In accordance with FIFRA, the Agency's policy is not to routinely cancel the registration of products or to withhold registration merely for the lack of data (see Sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, the publication of this Standard provides a mechanism for identifying data needs, and registration of temephos under this Standard allows for the upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency and the registerability of the chemical will be reassessed.

E. Criteria for Registration Under the Standard

To be subject to this Standard, temephos products must meet the following conditions:

- contain temephos as the sole active ingredient** and have the same use patterns described in this Standard;

- bear required labeling; and

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* Geomet Technologies, Rockville, Md., Contract No. 68015155 September 4, 1980.

** Note: Since petroleum distillates have little or no insecticidal activity in temephos products (e.g., emulsifiable concentrates), the Agency has determined that petroleum distillates should be considered as part of the inert ingredients. If the registrant wishes to declare petroleum distillates as active ingredients, supporting data must accompany the application for reregistration.

- conform to the acute toxicity limits, product composition, and use pattern requirements stated below.

The applicant for registration or reregistration of temephos products subject to this Standard must comply with all terms and conditions described in this Standard, including a commitment to fill data gaps on a time schedule specified by the Agency as indicated in Part III and, when applicable, offer to pay compensation to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136 (c)(2)(D). As discussed in Part I and in the Guidance Package, applicants for registration of temephos products under this Standard must contact the Agency for specific instructions, including updated information on data requirements, and companies whose data may be cited and to whom compensation must be offered.

1. Manufacturing-Use Temephos

a. Acceptable Ranges and Limits

i. Product Composition Standard

To be covered under this Standard, manufacturing-use temephos products must conform to the requirements stated below:

Active Ingredient: Any percentage acceptable.

ii. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use temephos products in the toxicity categories indicated by a "yes":

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

iii. Use Patterns

To be covered under this Standard, manufacturing-use temephos products must be labeled to allow for formulation into end-use insecticides which are intended only for:

1) outdoor, nondomestic, nonfood aquatic areas;
2) domestic use on cats and dogs, and in their living quarters;
3) domestic flea collars for cats and dogs; and
4) outdoor, nondomestic, food use on orange and tangerine trees (California and Arizona only).

iv. Required labeling

All manufacturing-use temephos products must bear appropriate labeling as specified in 40 CFR 162.10. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

Efficacy Statements

All manufacturing-use temephos products must list on the label the intended end-uses of formulated products produced from the manufacturing-use products. In accordance with data to be submitted or cited, all temephos product labels must bear one or a combination of the following statements:

1) "For Formulation into End-Use Insecticide Products Intended Only as an Insecticide for Nondomestic, Nonfood, Outdoor Aquatic Uses";

2) "For Formulation into End-Use Insecticide Products Intended Only as an Insecticide for Nondomestic, Outdoor, Food Use";

3) "For Formulation into End-Use Insecticide Products Intended for Cat and Dog Flea Collars"; and/or

4) "For Formulation into End-Use Insecticide Products Intended for Direct Application on Cats and Dogs, and in their Living Quarters."

Ecological Effects Statements

The following statements must appear under the heading "Environmental Hazards" [see Section 162.10(h)(2(ii) of the guidelines]:

> This pesticide is toxic to birds and fish. Do not discharge directly into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.

Additional fish and wildlife labeling may be required upon review of the requested studies (see Tables III.A-5 in Part III).

Product Chemistry Statements

The ingredient statement for manufacturing-use products must list the active ingredient as:

Temephos [O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl phosphorothioate)]................N% (min.)

There is currently no special hazard precautionary labeling for the manufacturing-use products. However, as required physical/chemical property data gaps are filled, the Agency may impose additional labeling requirements.

2. End-Use Temephos: Emulsifiable Concentrates

a. Acceptable Ranges and Limits

i. Product Composition Standard

To be covered under this Standard, emulsifiable concentrate products must conform to the requirements stated below:

Active ingredient:	Any percentage acceptable.
Inert ingredient:	Only those inert ingredients which are exempt from the requirements of a tolerance (see 40 CFR Section 180.1001) are acceptable for use on food crops. There are no restrictions on inert ingredients when used for nonfood purposes.

ii. Acute Toxicity Limits

The Agency will consider registration of emulsifiable concentrate temephos products in the toxicity categories indicated by "yes". The Agency will consider registration of products in toxicity category I when all of the acute toxicity data and other required data appropriate for an amended registration are satisfied. After receipt and review of these data, the Agency may require other appropriate data (e.g., special or subchronic

studies), impose additional labeling restrictions, or deny registration.

	I	II	III	IV
Acute oral toxicity	amendment required	yes	yes	yes
Acute dermal toxicity	amendment required	yes	yes	yes
Acute inhalation toxicity	amendment required	yes	yes	yes
Primary eye irritation	amendment required	yes	yes	yes
Primary dermal irritation	amendment required	yes	yes	yes

iii. Use Patterns

To be registered under this Standard, emulsifiable concentrate temephos products must be labeled as an insecticide for non-domestic use for one or more of the following uses: 1) food uses, orange and tangerine trees (California and Arizona only); and 2) nonfood crop aquatic uses, intermittently flooded areas, temporary rain pools, catch basins, standing water, woodland pools, shallow lakes and lake margins, log ponds, sloughs, stagnant water, marshes, tidal water, and swamps.

iv. Required labeling

All end-use emulsifiable concentrate temephos products must bear appropriate labeling as specified in 40 CFR 162.10. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

Product Chemistry Statements

The ingredient statement for end-use emulsifiable concentrate products must list the active ingredient as:

Temephos [O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl
phosphorothioate)]..................N% (min.)

There is currently no special hazard precautionary labeling for the end-use emulsifiable concentrate products. However, as required physical/chemical property data gaps are filled, the Agency may impose additional labeling requirements.

Efficacy Statements

Appropriate product dilution rates for application [e.g., milliliters product (liquid) per square feet] must be provided for spot treatment of areas such as catch basins, containers of water (e.g., old tires), and other water-filled sunken areas where mosquitoes may breed.

The following statement must appear on all temephos emulsifiable concentrates under the heading "Directions for Use":

> The higher rate should be used in areas known to have organic phosphate resistant mosquitoes.

Ecological Effects Statements

For those emulsifiable concentrates registered for use on tangerine and orange trees (California and Arizona only), the following labeling must appear under the heading "Environmental Hazards" [see Section 162.10(h)(2)(ii) of the guidelines]:

> This pesticide is toxic to birds and fish. Use with care when applying in areas frequented by wildlife or adjacent to any body of water. This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area. Do not contaminate water by cleaning of equipment or disposing of wastes.

Under "Directions for Use" for the emulsifiable concentrate for aquatic uses, the following labeling must be included:

> When using in lakes, ponds, tidal marshes, and estuaries, apply only in shallow water at the edge of these areas.

For those emulsifiable concentrates registered for aquatic uses, the following statements must be included on the labeling and appear under the headings "Environmental Hazards":

> This pesticide is toxic to birds and fish. Fish and other aquatic organisms in waters treated with this product may be killed. You must consult your State Fish and Game Agency before applying this product to waters or wetlands. Do not contaminate water by cleaning of equipment or disposing of wastes.

Additional fish and wildlife statements may be required upon review of the requested studies (see Table III.A-5 in Part III).

Residue Chemistry Statements

The labeling for formulations used on citrus bears two restrictions: 1) "on bearing trees the product is to be applied at prebloom or at petal fall only after harvest of mature fruit. This product should not be applied to any varieties of citrus when immature fruit are present during prebloom and petal fall. Do not apply during bloom period." and 2) "use restricted to Arizona and California". These restrictions must continue to appear on the labeling for the food crop use.

In lieu of submitting required data on residues in cover crops in temephos-treated citrus orchards, the following statement must appear on the labeling:

> Do not feed or allow livestock to graze on cover crops grown in treated orchards.

Products for use on aquatic sites (e.g., catch basins, shallow lakes and lake margins, sloughs, marshes, tidal water, swamps) must continue to bear the restriction against use of the product on crops for food, forage, or pasture. Because of the large number of aquatic sites on which temephos may be used, residues may appear in potable water, fish, irrigated crops and livestock. Upon receipt and evaluation of data on the degradation of temephos in water and fish, the following labeling statements may be required:

> Do not apply to the following aquatic sites: 1) potable water, 2) water used for irrigating crops, 3) water used for watering livestock, and 4) water containing edible fish. Do not drain treated water into a flowing stream that is a potential source of water for one or more of the above uses.

In lieu of labeling restrictions, appropriate tolerances for potable water, fish, shellfish, irrigated crops, meat, milk, poultry and eggs may be necessary. Other labeling restrictions may be imposed as the required residue data gaps are filled.

3. End-Use Temephos: Granular

a. Acceptable Ranges and Limits

i. Product Composition Standard

To be covered under this Standard, granular temephos products must conform to the requirements stated below:

Active ingredient: Any percentage acceptable.

Inert ingredient: There are no restrictions on inert ingredients when used for nonfood purposes.

ii. Acute Toxicity Limits

The Agency will consider registration of granular temephos products in the toxicity categories indicated by "yes". The Agency will consider registrations of products in toxicity category I when all of the acute toxicity data and other required data appropriate for an amended registration are satisfied. After receipt and review of these data, the Agency may require other appropriate data (e.g., special or subchronic

studies), impose additional labeling restrictions, or deny registration.

	I	II	III	IV
Acute oral toxicity	amendment required	yes	yes	yes
Acute dermal toxicity	amendment required	yes	yes	yes
Acute inhalation toxicity	amendment required	yes	yes	yes
Primary eye irritation	amendment required	yes	yes	yes
Primary dermal irritation	amendment required	yes	yes	yes

iii. Use Patterns

To be registered under this Standard, granular temephos products must be labeled as an insecticide for one or more of the following nonfood crop aquatic uses: sloughs, stagnant water, log ponds, temporary rain pools, intermittently flooded areas, catch basins, lakes, standing water, shallow ponds, woodland pools, tidal water, marshes, swamps, water high in organic matter, highly polluted water, marshlands and intertidal zones of sandy beaches.

iv. Required Labeling

All granular temephos products must bear appropriate labeling as specified in 40 CFR 161.10. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

Product Chemistry Statements

The ingredient statement for end-use granular products must list the active ingredient as:

Temephos [O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl phosphorothioate)]................N% (min.)

There is currently no special hazard precautionary labeling for the end-use granular products. However, as required physical/chemical property data gaps are filled, the Agency may impose additional labeling requirements.

Efficacy Statements

Appropriate product dilution rates for application [e.g., grams product (weight) per square feet] must be provided for spot treatments of areas such as catch basins, containers of water (e.g., old tires), and other water-filled sunken areas where mosquitoes may breed.

The following statement must appear on all temephos granular products under the heading "Directions for Use":

> The higher rate should be used in areas known to have organic phosphate resistant mosquitoes.

Ecological Effects Statements

The following statements must appear on granular temephos products for aquatic uses under the heading "Environmental Hazards":

> This pesticide is toxic to birds and fish. Fish and other aquatic organisms in water treated with this product may be killed. You must consult your State Fish and Game Agency before applying this product to waters or wetlands. Do not contaminate water by cleaning of equipment or disposing of wastes.

Additional fish and wildlife labeling may be required when the Agency reviews the requested studies (see Table III.A-5 in Part III).

Residue Chemistry Statements

Products for use on aquatic sites (e.g., sloughs, catch basins, lakes, shallow ponds, tidal water, marshes, swamps, water high in organic content, highly polluted water, marshlands, intertidal zones of sandy beaches) must continue to bear the restriction against use of the product on crops for food, forage, or pasture. Because of the large number of aquatic sites on which temephos may be used, residues may appear in potable water, fish, irrigated crops and livestock. Upon receipt and evaluation of data on the degradation of temephos in water and fish, the following labeling statements may be required:

> Do not apply to the following aquatic sites: 1) potable water, 2) water used for irrigating crops, 3) water used for watering livestock, and 4) water containing edible fish. Do not drain treated water into a flowing stream that is a potential source of water for one or more of the above uses.

In lieu of labeling restrictions, appropriate tolerances for potable water, fish, shellfish, irrigated crops, meat, milk, poultry and eggs may be necessary. Other labeling restrictions may be imposed as the required residue data gaps are filled.

4. End-Use Temephos: Dusts

a. Acceptable Ranges and Limits

i. Product Composition Standard

To be covered under this Standard temephos dust products must conform to the requirements stated below:

Active ingredient:	Any percentage acceptable.
Inert ingredients:	There are no restrictions on inert ingredients when used for nonfood purposes.

ii. Acute Toxicity Limits

The Agency will consider registration of temephos dust products in the toxicity categories indicated by "yes". The Agency will consider registration of products in toxicity categories I and II when all of the acute toxicity data and other required data appropriate for an amended registration are satisfied. After receipt and review of these data, the Agency may require other appropriate data (e.g., special or subchronic studies), impose additional labeling restrictions, or deny registration.

	I	II	III	IV
Acute oral toxicity	amendment required	amendment required	yes	yes
Acute dermal toxicity	amendment required	amendment required	yes	yes
Acute inhalation toxicity	amendment required	amendment required	yes	yes
Primary eye irritation	amendment required	amendment required	yes	yes
Primary dermal irritation	amendment required	amendment required	yes	yes

iii. Use Patterns

To be registered under this Standard, temephos dust products must be labeled as an insecticide for the following domestic uses: direct application on dogs and cats, and in their living quarters.

iv. Required Labeling

All temephos dust products must bear appropriate labeling as specified in 40 CFR 162.10. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

Product Chemistry Statements

The ingredient statement for end-use dust products must list the active ingredient as:

Temephos [O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl
phosphorothioate)]..................N% (min.)

There is currently no special hazard precautionary labeling for the end-use dust products. However, as required physical/chemical property data gaps are filled, the Agency may impose additional labeling requirements.

5. End-Use Temepnos: Impregnated Material

a. Acceptable Ranges and Limits

i. Product Composition Standard

To be covered under this Standard, impregnated temephos products must conform to the requirements stated below:

Active ingredient:	Any percentage acceptable.
Inert ingredients:	There are no restrictions on inert ingredients used for nonfood purposes.

ii. Acute Toxicity Limits

The Agency will consider registration of impregnated temephos products in the toxicity categories indicated by "yes". The Agency will consider registration of products in toxicity categories I and II when all of the acute toxicity data and other required data appropriate for an amended registration are satisfied. After receipt and review of these data, the Agency may require other appropriate data (e.g., special or subchronic

studies), impose additional labeling restrictions, or deny registration.

	I	II	III	IV
Acute oral toxicity	amendment required	amendment required	yes	yes
Acute dermal toxicity	amendment required	amendment required	yes	yes
Acute inhalation toxicity	amendment required	amendment required	yes	yes
Primary eye irritation	amendment required	amendment required	yes	yes
Primary dermal irritation	amendment required	amendment required	yes	yes

iii. Use Patterns

To be registered under this Standard, a product impregnated with temephos must be labeled as an insecticide for the following domestic uses: cat and dog flea collars.

iv. Required Labeling

All temephos-impregnated cat and dog collar products must bear appropriate labeling as specified in 40 CFR 162.10. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

Product Chemistry Statements

The ingredient statement for end-use impregnated material products must list the active ingredient as:

Temephos [O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl
phosphorothioate)]................N% (min.)

There is currently no special hazard precautionary labeling for the end-use impregnated material products. However, as required physical/chemical property data gaps are filled, the Agency may impose additional labeling requirements.

F. Tolerance Reassessment

To provide for the use of temephos on orange and tangerine trees in Arizona and California, a tolerance of 0.1 ppm has been established for combined negligible residues of temephos and its sulfoxide in or on the raw agricultural commodity, citrus fruits (40 CFR 180.170). Based on the established tolerance, the theoretical maximum residue contribution (TMRC) of temephos to the human diet is calculated to be 0.0057 mg/1.5 kg diet/day. However, because there is some uncertainty about the nature of the residue on temephos-treated citrus, the tolerance from which the TMRC is calculated may not be adequate (the current method for detecting temephos residues does not detect residues other than temephos and its sulfoxide). A tolerance reassessment is consequently not possible at this time (August, 1981). A reassessment will be performed after the Agency receives and reviews the data listed in Table III.A-4, Residue Chemistry (Part VII) and Table III.A-3, Toxicology (Part VI)*.

Codex Maximum Residue Limits (MRL's) have not been established for temephos. Currently, there are no Canadian or Mexican tolerances for temephos.

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* The Agency requires the submittal of these data (i.e., Residue Chemistry and Toxicology) to maintain the tolerance which provides for temephos use on imported citrus as well as on citrus growing in the United States. If these data (see Part III, Table III.A, e.g., residue, toxicity) are not provided to the Agency to evaluate the possible hazards to man and other nontarget species from the potential effects of its use, the Agency will propose revocation of the tolerance under the Federal Insecticide, Fungicide and Rodenticide Act, 40 CFR Section 180.001 and the Food and Drug Cosmetic Act, 21 CFR Section 408(e).

III. Summary of Data Requirements

Applicants for registration of manufacturing-use and end-use temephos products must cite or submit the information identified as required in the tables in this part. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or the formulation. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation based on the chemical composition as indicated by the Confidential Statement of Formula (CSF). Information on which product-specific data requirements are already satisfied is available in the Guidance Package and in Tables III.A through C in this Standard.

Preceeding each requirement, with the exception of Residue Chemistry and Efficacy*, is listed the Proposed Guidelines which describe the type of data and when the data are required to be submitted. Justification for the test requirement is provided in the Guidelines (see 43 FR 29696 of July 10, 1978; 43 FR 37336 of August 22, 1978; and 45 FR 72948 of November 3, 1980). A discussion of why data additional to that already submitted are necessary, or why data usually required are not necessary for this chemical, are explained in footnotes to the tables. The specified data requirements are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated (see tables for Toxicology, Residue Chemistry, and Ecological Effects in this part).

Bibliographic citations in the following tables indicate that the listed study accomplishes one of the following:

1) provides all the information required by the guideline requirement;

2) provides partial information required by the guideline requirement; and

3) provides specific information that is elaborated on by an accompanying footnote.

Bibliographic citations noted in Parts IV through IX which are not listed in this part are provided as reference and background material to the reader; they do not relate directly to or satisfy the guideline requirements.

The word "yes" under the heading "Does EPA have data to partially or totally satisfy this requirement?" means that the requirement has been satisfied, unless otherwise noted.

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* There are currently no Proposed Guidelines for Efficacy. Refer to Part I.D for discussion of registrants' familiarity of data requirements for Residue Chemistry.

In some cases the data requirements are imposed by the use patterns and the use patterns appear in the tables under the heading "Are data required by this Standard?" (see Tables III.A-2, 3, 4, and 5). Where only the word "yes" appears under this heading, the data requirements are required for all currently registered products, regardless of use pattern.

A. Table III.A Generic Data Requirements

This table includes those data that pertain to the properties or effects of temephos as an active ingredient. Thus, these data are relevant to an evaluation of the risks of all products containing temephos. Providing data to fill indicated gaps in the data base is the primary responsibility of the registrant(s) of manufacturing-use temephos. Registrants of end-use products which are not exempted by FIFRA Section 3(c)(2)(D) are also responsible for the submission of these data.

However, applicants for the registration of end-use products containing temephos are advised that if the Agency does not receive commitments within the time specified in the tables from manufacturing-use temephos registrant(s) to fill data gaps identified for the manufacturing-use product (Table III.A), manufacturing-use product registrations will be suspended. Formulators must then bear the burden of supplying these data in both Table III.A and B if continued registration of their product is desired.

Applicants for the registration or reregistration of manufacturing-use temephos products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA Section 3(c)(1)(D). These data are listed under the column "Bibliographic Citation" in Table III.A.

B. Table III.B Product-Specific Data Requirements for Manufacturing-Use Products

This table includes those data that relate only to the properties or effects of a product with a specific composition (or substantially similar composition). Thus, these data are required of each product (or substantially similar product) to characterize the product's particular composition and physical/chemical properties, and to characterize the product's acute toxicity.

Product compostion data, physical/chemical properties and acute toxicity are required for each manufacturing-use product. Providing data to fulfill these requirements is the responsibility of each applicant for the registration or reregistration of a manufacturing-use temephos product. If the Agency has data which fulfills this requirement for a particular product(s), this is indicated in the table and in the Guidance Package accompanying this Standard.

Product-specific data need not be acknowledged under FIFRA Section 3(c)(1)(D) unless the Agency has established that one product is substantially similar to another product for which the Agency has received acceptable data.

C. Table III.C Product-Specific Data Requirements for End-Use Products

This table includes those data that relate only to the properties or effects of a product with a specific composition (or substantially similar composition). Thus, these data are required of each product (or substantially similar product) to characterize the product's particular composition and physical/chemical properties, and to characterize the product's acute toxicity.

Product compostion data, physical/chemical properties and acute toxicity are required for each end-use product. Providing data to fulfill these requirements is the responsibility of each applicant for the registration or reregistration of an end-use temephos product. If the Agency has data which fulfills this requirement for a particular product(s), then this is indicated in the table and in the Guidance Package accompanying this Standard.

Product-specific data may be acknowledged under FIFRA Section 3(c)(1)(D) only if the Agency has established that one product is substantially similar to another product for which the Agency has received acceptable data.

Table III.A-1 Generic Data Requirements for Temephos, Product Chemistry, (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-3	Product Identity and Disclosure of Ingredients	yes	Technical grade of active ingredient	partial[1]	000003268, 000001216	yes/8 months
163.61-8(1)	Color	yes	Technical grade of active ingredient	yes	000001379	no
163.61-8(2)	Odor	yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-8(3)	Melting Point	yes	Technical grade of active ingredient	yes	000001379	no
163.61-8(4)	Solubility	yes	Technical grade of active ingredient	partial[2]	000001379	yes/8 months
163.61-8(5)	Stability	yes	Technical grade of active ingredient	yes	000001379	no
163.61-8(6)	Octanol/Water partition coefficient	yes	Techncial grade of active ingredient	no	-	yes/8 months

Table III.A-1 Generic Data Requirements for Temephos, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-8(7)	Physical State	yes	Technical grade of active ingredient	yes	000003264	no
163.61-8(8)	Density or Specific Gravity	yes	Technical grade of active ingredient	yes	000001379	no
163.61-8(9)	Boiling Point	yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-8(10)	Vapor Pressure	yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-8(11)	pH	yes	Technical grade of active ingredient	no	-	yes/8 months

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1/ The impurities exceeding 0.1% of the technical temephos product weight must be determined.

2/ A numerical value for solubility of temephos in organic solvents must be determined.

August, 1981

Table III.A-2 Generic Data Requirements for Temephos, Environmental Fate (see Part V)

Guidelines Citation	Name of Test	Are Data Required for this Standard?		Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.62-7(b)	Hydrolysis		yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/8 months
163.62-7(c)	Photodegradation	Food crops Aquatic	yes yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/12 months
163.62-8(b)	Aerobic soil metabolism	Food crops	yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/36 months
163.62-8(d)	Anaerobic aquatic metabolism	Aquatic	yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/18 months
163.62-8(e)	Aerobic aquatic metabolism	Aquatic	yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/18 months
163.62-8(f)	Microbial metabolism (2) effects of microbes on pesticides	Food crops Aquatic	yes yes	1/	no	-	1/

Table III.A-2 Generic Data Requirements for Temephos, Environmental Fate (see Part V) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?		Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.62-8(f)	Microbial metabolism (cont'd)					-	
	(3) effects of pesticides on microbes	Food crops Aquatic	yes yes	1/	no	-	1/
163.62-8(g)	Activated sludge metabolism		yes	1/	no	-	1/
163.62-9(b)	Leaching[2]	Food crops	yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/12 months
163.62-9(d)	Adsorption/[3] desorption	Food crops Aquatic	yes yes	Radiolabeled analytical grade or technical grade of active ingredient	no	-	yes/12 months
163.82-9(e)	Water dispersal	Aquatic	yes	Representative formulated product[4]	no	-	yes/14 months
163.62-10(b)	Terrestrial field dissipation						
	(2) Tree fruit and nut crop uses	Food crops	yes	Representative formulated emulsifiable concentrate (43-60%) made from each MUP (preferably the highest concentrated (ai) product	no	-	yes/28 months

Table III.A-2 Generic Data Requirements for Temephos, Environmental Fate (see Part V) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?		Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.62-10(c)	Aquatic field dissipation (2) Aquatic noncrop aquatic	Aquatic	yes	Representative formulated product[4/]	no	-	yes/14 months
163.62-10(d)	Terrestrial/ aquatic (forest) field dissipation	Aquatic	yes	Representative formulated product[4/]	no	-	yes/14 months
163.62-10(e)	Aquatic impact uses						
	(1) Direct discharge	Aquatic	5/				
	(2) Indirect discharge	Aquatic	6/				
163.62-11(c)	Accumulation in irrigated crops	Aquatic	yes	Representative formulated product[4/]	no	-	yes/14 months
163.62-11(d)	Fish accumulation	Food crops Aquatic	yes yes	Radiolabeled analytical grade or technical grade of active ingredient	partial[7/]	005000978	yes/12 months
163.62-11(e)	Special studies; accumulation in aquatic noncrop uses	Aquatic	yes	Technical grade of active ingredient	no	-	yes/18 months

Table III.A-2 Generic Data Requirementsfor Temephos, Environmental Fate (see Part V) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.62-13	Disposal and storage	yes	Technical grade of active ingredient and all formulations	no	-	1/

1/ The requirement for submission of these data is currently being reserved pending the review and modification of testing protocols.

2/ For terrestrial noncrop uses, orchard crop uses, field vegetable crop uses, and forestry uses, the mobility of the test substance and its degradates in soil shall be assessed either by soil thin-layer chromatography, soil column, or batch equilibrium (adsorption/desorption) procedures.

3/ For domestic outdoor uses, greenhouse uses, aquatic uses, and aquatic impact-direct discharge uses, the mobility of the test substance and its degradates in soil shall be assessed only by the batch equilibrium (adsorption/desorption) procedure.

4/ Any currently registered formulated emulsifiable concentrate which contains 43-60% temephos and any formulated granular containing 1%, 2% or 5% temephos made from each manufacturing-use product (MUP).

5/ Data necessary to meet this requirement will be provided by data from 163.62-7(b) and (c); 163.62-8(d), (e), (f), and (g); 163.62-9(d); 163.62-10(c); and 163.62-11(d).

6/ Data necessary to meet this requirement will be provided by data from 163.62-7(b) and 163.62-8(g).

7/ Additional studies are required to measure the effects of temephos on fish in a flow through environment.

August, 1981

Table III.A-3 Generic Data Requirements for Temephos, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.81-1	Acute Oral Toxicity	yes	Technical grade of active ingredient	yes	000001365, 000001354, 000001368, 005000974	no
163.81-2	Acute Dermal Toxicity	yes	Technical grade of active ingredient	yes	000001354, 005000974, 000001252	no
163.81-3	Acute Inhalation Toxicity	yes	Technical grade of active ingredient	partial	000001252	yes/8 months[1/]
163.81-4	Primary Eye Irritation	yes	Technical grade of active ingredient	yes	000001352	no
163.81-5	Primary Dermal Irritation	yes	Technical grade of active ingredient	no	-	no[2/]
163.81-6	Dermal Sensitization	yes	Technical grade of active ingredient	no	-	yes/8 months

Table III.A-3 Generic Data Requirements for Temephos, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?		Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.81-7	Acute Delayed Neurotoxicity		yes	Technical grade of active ingredient	no	-	yes/24 months[3]
163.82-1	Subchronic Oral Toxicity	Food crops	yes	Technical grade of active ingredient	yes	000001239, 005001356, 000001240, 000001252	no
163.82-5	Subchronic Neurotoxicity		yes	Technical grade of active ingredient	no	-	yes/18 months[4]
163.83-1	Chronic Feeding Study	Food crops	yes	Technical grade of active ingredient	yes	000001386	no
163.83-2	Oncogenicity	Food crops	yes	Technical grade of active ingredient	partial[5]	000001386	yes/36 months
163.83-3	Teratogenicity	Food crops Pets and their living quarters Flea collars	yes yes yes	Technical grade of active ingredient	no	-	yes/36 months

Table III.A-3 Generic Data Requirements for Temephos, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.82-4	Reproduction	Food crops yes	Technical grade of active ingredient	yes	000001388	no
163.84-1 163.84-2 163.84-3 163.84-4	Mutagenicity	Food crops yes Pets and their living quarters yes Flea collars yes	Technical grade of active ingredient	no	-	yes/24 months
163.85-1	Metabolism	Food crops yes	Radiolabeled analytical grade	yes	000001376, 005000858 005000806, 000001343	no

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1/ This study will be considered valid if data are submitted to support the statement in the study that the test concentration was at a saturation level. If this information is not provided or considered invalid, further testing will be required.

2/ Since the technical formulation is not irritating to the eyes of test animals, skin irritation is assumed to be unlikely. The data for 163.81-5 are not required.

3/ This test is required because temephos is expected to cause cholinesterase depression.

4/ The requirement for this test is contingent upon the results of the acute delayed neurotoxicity test (see 163.81-7).

5/ The above cited oncogenicity study, while acceptable, must be supplemented by a confirmatory second study (18 months) using the mouse as the test species.

Table III.A-4 Generic-Data Requirements for Temephos, Residue Chemistry (see Part VII)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
-	Metabolism in Plants	Food crops yes	Technical grade of active ingredient [1]	partial[2]	000001377	yes/24 months
-	Metabolism in Animals	Food crops yes	Technical grade of active ingredient [1]	yes	000001403, 000001343, 000001344	no
-	Storage Stability	Food crops yes	Technical grade of active ingredient	no	-	yes/24 months
-	Analytical Methods	Food crops yes	Technical grade of active ingredient	yes	005000638	no[3]
-	Residue Data:					
	1. Mature Citrus	Food crops yes	Technical grade of active ingredient	partial	000001402	yes/24 months[4]
	2. Citrus by-products	Food crops yes	Technical grade of active ingredient	no	-	yes/24 months[4]

Table III.A-4 Generic-Data Requirements for Temephos, Residue Chemistry (see Part VII) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
-	Residue Data: (cont'd)					
	3. Cover Crops Food crops	yes	Technical grade of active ingredient	no	-	yes/24 months[5/]

1/ The ^{14}C-active ingredient should be used.

2/ Data are available on the metabolism of temephos applied to bean leaves. Data are required for 1) the fate of temephos in citrus (or a demonstration that the fate of temephos in a variety of food crops is similar); 2) the uptake of temephos from soil; and 3) the fate of temephos under field conditions.

3/ If other toxicologically significant metabolites are found during the course of plant metabolism studies, analytical methods for their determination must be submitted.

4/ These test data will not be required if metabolism data show that residues other than temephos and temephos sulfoxide are insignificant in plants.

5/ In lieu of acquiring residue data on cover crops in temephos-treated citrus orchards, a restriction against the grazing or feeding of temephos-treated cover crops to livestock may be imposed.

August, 1981

Table III.A-5 Generic Data Requirements for Temephos, Ecological Effects (see Part VIII)

Guidelines Citation	Name of Test	Are Data Required for this Standard?		Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.71-1	Avian Single Dose Oral LD_{50}	Food crops Aquatic	yes yes	Technical grade of active ingredient	partial[1]	005000975, GS0006004	yes/16 months
163.71-2	Subacute Dietary toxicity (avian dietary LC_{50})	Food crops Aquatic	yes yes	Technical grade of active ingredient	yes	000001384, 000022923	no
163.72-1	Fish Acute LC_{50}	Food crops	yes	Technical grade of active ingredient	yes	005000819, GS0006006, GS0006005	no
		Aquatic	yes	Emulsifiable Concentrate	yes[2]	000001337, GS0006005	no
				Granular	no	-	yes/8 months
163.72-2	Acute Toxicity to Aquatic Invertebrates	Food crops	yes	Technical grade of active ingredient	yes	GS0006005	no
		Aquatic	yes	Emulsifiable Concentrate	no	-	yes/8 months
				Granular	yes[3]	GS0006007	no
163.72-3	Acute Toxicity to Estuarine and Marine Organism	Food crops	yes	Technical grade of active ingredient	no	-	yes/16 months
		Aquatic	yes	Emulsifiable Concentrate	no	-	yes/8 months
				Granular	no	-	yes/8 months

Table III.A-5 Generic Data Requirements for Temephos, Ecological Effects (see Part VIII) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.72-4	Embryolarvae and Life-cycle Studies of Fish and Aquatic Invertebrates	Food crops yes Aquatic yes	4/	no	-	4/
163.72-5	Aquatic Organism Toxicity and Residue Studies	Food crops yes Aquatic yes	4/	no	-	4/
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	Food crops yes Aquatic yes	5/	no	-	5/
163.122-1	Seed Germination/ Seedling Emergence and Vegetative Vigor (Tier I)	Food crops yes Aquatic yes	Technical grade of active ingredient	no	-	yes6/
163.122-2	Growth and Reproduction of Aquatic Plants (Tier I)	Food crops yes Aquatic yes	Technical grade of active ingredient	no	-	yes6/

1/ Additional data are needed on dose response, age of test species and specific LD_{50} values.

2/ For the 43% emulsifiable concentrate.

3/ For 5% or less granular formulations.

4/ Data are being reserved pending results of tests pertaining to Guidelines 163.72-1, 2 and 3.

5/ Data are being reserved pending results of tests pertaining to Guidelines 163.72-4 and 5.

6/ A 48 month time period will be allowed from the time of acceptance of the Non-Target Plant Hazard Evaluation Guidelines.

Table III.B-1 Product-Specific Requirements for Manufacturing-Use Products, Product Chemistry[1] (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-3	Product Identity and Disclosure of Ingredients	yes	each manufacturing-use product	yes[2]	-	no
163.61-4	Description of manufacturing process	yes	each manufacturing-use product	no	-	yes/8 months
163.61-5	Discussion on formation of unintentional ingredients	yes	each manufacturing-use product	no	-	yes/8 months
163.61-6	Declaration and certification of ingredients limits	yes	each manufacturing-use product	no	-	yes/8 months
163.61-7	Product analytical methods and data	yes	each manufacturing-use product	partial[3]	005000638	yes/8 months
163.61-8(7)	Physical State	yes	each manufacturing-use product	yes[2]	-	no
163.61-8(8)	Density or Specific Gravity	yes	each manufacturing-use product	partial[4]	-	yes/8 months

Table III.B-1 Product-Specific Requirements for Manufacturing-Use Products, Product Chemistry[1] (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-8(11)	pH	yes	each manufacturing-use product	no	-	yes/8 months
163.61-8(12)	Storage Stability	yes	each manufacturing-use product	no	-	yes/8 months
163.61-8(13)	Flammability	yes	each liquid manufacturing-use product	partial[5]	-	yes/8 months
163.61-8(14)	Oxidizing or Reducing Action	yes	each manufacturing-use product	no	-	yes/8 months
163.61-8(15)	Explosiveness	yes	each manufacturing-use product	no	-	yes/8 months
163.61-8(16)	Miscibility	yes	each liquid manufacturing-use product	partial[6]	-	yes/8 months
163.61-8(17)	Viscosity Coefficient	yes	each liquid manufacturing-use product	no	-	yes/8 months
163.61-8(18)	Corrosion Characteristics	yes	each manufacturing-use product	no	-	yes/8 months

Table III.B-1 Product-Specific Requirements for Manufacturing-Use Products, Product Chemistry[1] (see Part IV) (cont'd)

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[1] Even though some of the requirements have been partially or completely fulfilled for some products, the references cannot be cited to support other products, except for 163.61-7. These requirements must be resubmitted by each applicant at the time of registration or reregistration.

[2] The Agency has information to support all currently registered manufacturing-use products [information was provided in the Confidential Statements of Formula (CSF)].

[3] The analytical method for the active ingredient is of sufficient detail to satisfy the Agency's requirement, but validation data and results of analysis must be submitted. Analytical methods and validation data must be submitted for the impurities for each manufacturing-use product.

[4] The Agency has information to support EPA Reg. No. 241-242 (CSF). This data must be submitted for other manufacturing-use products.

[5] The Agency has information to support EPA Reg. No. 241-242 (CSF). This data must be submitted for other manufacturing-use products.

[6] The Agency has information to support EPA Reg. No. 241-242 (MRID #000001379). This data must be submitted for other manufacturing-use products.

Table III.B-2 Data Requirements for Manufacturing-Use Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.81-1	Acute Oral Toxicity	yes	25% concentrate dust[1]	yes	000001307	no
			70% concentrate[1]	yes	000001352	no
163.81-2	Acute Dermal Toxicity	yes	25% concentrate dust[1]	yes	000001307	no
			70% concentrate[1]	yes	000001352	no
163.81-3	Acute Inhalation Toxicity	yes	-	no	-	no[2]
163.81-4	Primary Eye Irritation	yes	25% concentrate dust[1]	yes	000001307	no
			70% concentrate[1]	yes	000001352	no
163.81-5	Primary Dermal Irritation	yes	25% concentrate dust[1]	yes[3]	000001352	no
			70% concentrate[1]	yes	000001352	no
163.81-6	Dermal Sensitization	yes	25% concentrate dust[1] 70% concentrate[1]	no	-	no[2]

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[1] Each manufacturing-use product or substantially similar product based on Confidential Statement of Formula.

[2] Based on Confidential Statements of Formula; testing of the technical grade of the active ingredient will be sufficient to satisfy this requirement.

[3] The study conducted on the 70% concentrate (MRID #000001352) is also adequate to support the testing requirements on the 25% concentrated dust product.

Table III.C-1 Product-Specific Data Requirements for End-Use Temephos Products, Product Chemistry[1] (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-3	Product Identity and Disclosure of ingredients	yes	each product	yes[2]	-	no
163.61-4	Description of manufacturing process	yes	each product	partial[3]	000001267	yes/8 months
163.61-5	Discussion of formation of unintentional ingredients	yes	each product	no	-	yes/8 months
163.61-6	Declaration and certification of ingredient limits	yes	each product	no	-	yes/8 months
163.61-7	Product analytical methods and data	yes	each product	partial[4]	005000638	yes/8 months
163.61-8(1)	Color	yes	each product	partial[5]	-	yes/8 months
163.61-8(2)	Odor	yes	each product	partial[5]	-	yes/8 months

Table III.C-1 Product-Specific Data Requirements for End-Use Temephos Products, Product Chemistry[1/] (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-8(7)	Physical State	yes	each product	yes[2/]	-	no
163.61-8(8)	Density or Specific Gravity	yes	each product	partial [6/]	-	yes/8 months
163.61-8(11)	pH	yes	each product	no	-	yes/8 months
163.61-8(12)	Storage Stability	yes	each product	no	-	yes/8 months
163.61-8(13)	Flammability	yes	each liquid product	partial[7/]	-	yes/8 months
163.61-8(14)	Oxidizing or Reducing Action	yes	each product	no	-	yes/8 months[8/]
163.61-8(15)	Explosiveness	yes	each product	no	-	yes/8 months[8/]
163.61-8(16)	Miscibility	yes	each liquid	no	-	yes/8 months

Table III.C-1 Product-Specific Data Requirements for End-Use Temephos Products, Product Chemistry[1] (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.61-8(17)	Viscosity Coefficient	yes	each liquid product	partial[9]	-	yes/8 months
163.61-8(18)	Corrosion characteristics	yes	each product	no	-	yes/8 months[8]

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[1] Even though some of the requirements have been partially or completely fulfilled for some products, references cannot be cited to support other products, except for 163.61-7. These requirements must be resubmitted by each applicant at the time of registration or reregistration.

[2] The Agency has information to support all currently registered end-use products [information was provided in the Confidential Statement of Formula (CSF)].

[3] The Agency has partial information to support flea collar products, but lacks information on the amount of starting materials (MRID #000001267). This data must be submitted for other end-use products.

[4] The analytical method for the active ingredient is of sufficient detail to satisfy the Agency's requirement, but validation data and results of analysis must be submitted.

[5] The Agency has information to support EPA Reg. No. 241-132 (MRID #000001254). This data must be submitted for other end-use products.

[6] The Agency has information to support EPA Reg. No. 241-223 (CSF) and EPA Reg. No. 802-495 (MRID #000001379). This data must be submitted for other end-use products.

[7] The Agency has information to support EPA Reg. No. 241-132 (CSF) and EPA Reg. No. 241-223 (CSF). This data must be submitted for other end-use products.

[8] Based on the Confidential Statement of Formula, these data will not be required on the currently registered impregnated materials.

[9] The Agency has information to support EPA Reg. No. 241-132 (MRID #000001379). This data must be submitted for other end-use products.

Table III.C-2.a. Product-Specific Data Requirements for End-Use Temephos Products, Toxicology (see Chapter VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition Impregnated Material (40.7%)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
-	Impregnated[1] Material Test	yes	each product	no	-	yes[2]

1/ Study must be conducted on animal at risk (e.g., dog, cat) at the following dose levels: vehicle control, the proposed use level, and five times the proposed use level. Cholinesterase activities must be measured and animals observed for signs of dermal irritation. See Guideline sections 163.86-1 for general guidance and 163.82-1 for specific guidance for conducting toxicology studies.

2/ Additional test protocols may be developed, especially in the area of child safety requirements.

August, 1981

Table III.C-2.b. Product-Specific Data Requirements for End-Use Temephos Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition Emulsifiable Concentrate (43-60%)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.81-1	Acute Oral Toxicity	yes	1/	yes	000001354, 000001353	no
163.81-2	Acute Dermal Toxicity	yes	1/	yes	000001354, 000001353	no
163.81-3	Acute Inhalation Toxicity	yes	1/	yes	000001354	no
163.81-4	Primary Eye Irritation	yes	1/	no	-	yes/8 months
163.81-5	Primary Dermal Irritation	yes	1/	yes	000001354	no
163.81-6	Dermal Sensitization	yes	1/	no	-	no2/

1/ Each product or substantially similar product, based on Confidential Statement of Formula.

2/ Based on Confidential Statement of Formula, testing of the technical grade of the active ingredient will be sufficient to satisfy this requirement.

August, 1981

Table III.C-2.c. Product-Specific Data Requirements for End-Use Temephos Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition Granular (1, 2, & 5%)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.81-1	Acute Oral Toxicity	yes	[1]	yes	000001308, 000001233	no
163.81-2	Acute Dermal Toxicity	yes	[1]	yes	000001308, 000001233	no
163.81-3	Acute Inhalation Toxicity	yes	[1]	no	-	no[2]
163.81-4	Primary Eye Irritation	yes	[1]	yes	000001308, 000001233	no
163.81-5	Primary Dermal Irritation	yes	[1]	yes	000001233	no
163.81-6	Dermal Sensitization	yes	[1]	no	-	no[2]

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[1] Each end-use product or substantially similar product, based on Confidential Statement of Formula.

[2] Based on Confidential Statement of Formula, testing of the technical material will be sufficient to satisfy this requirement.

Table III.C-2.d. Product-Specific Data Requirements for End-Use Temephos Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition Dust (2%)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
163.81-1	Acute Oral Toxicity	yes	1/	yes	000001308, 000001233	no
163.81-2	Acute Dermal Toxicity	yes	1/	yes	000001308, 000001233	no
163.81-3	Acute Inhalation Toxicity	yes	1/	no	-	no[2/]
163.81-4	Primary Eye Irritation	yes	1/	yes	000001308, 000001233	no
163.81-5	Primary Dermal Irritation	yes	1/	yes	000001233	no
163.81-6	Dermal Sensitization	yes	1/	no	-	no[2,3/]
163.82-2	21-Day Dermal Sensitization	yes	1/	no	-	yes/8 months[4/]

1/ Each end-use product or substantially similar product, based on Confidential Statement of Formula.

2/ Based on Confidential Statements of Formula, testing of the technical material will be sufficient to satisfy this requirement.

3/ In addition to the guideline data (163.81-6), additional test protocols may be developed, especially in the area of child safety requirements.

4/ For dog and cat use, testing is required and must include an adequate cholinesterase analysis of the animals at risk.

August, 1981

Table III.C-3 Product-Specific Products Data Requirements for End-Use Temephos, Efficacy (see Part IX)

Aquatic Sites	Name of Pest	Are Data Required for this Standard?	Composition and Active Ingredient/ Acre (AI/A)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
Sloughs, stagnant water, log ponds, temporary rain pools, intermittently flooded areas, catch basins, lakes, standing water, shallow ponds, woodland ponds	Mosquito larvae	yes	1,2 and 5% Granular (0.05 to 0.1 lb AI/A)	yes	000001338, 000003267, 000001400, 005000925	no
Tidal water, marshes, swamps, water high in organic matter	Mosquito larvae	yes	1,2 and 5% Granular (0.1 to 0.2 lb AI/A)	yes	000001245, 000001398, 000001397	no
Highly polluted water	Mosquito larvae	yes	2 and 5% Granular (0.5 lb AI/A)	yes	005000637, 005001004, 005000730	no
Marshlands and intertidal zones of sandy beaches	Biting midge larvae (punky and sand fly larvae)	yes	2 and 5% Granular (0.2 lb AI/A)	yes	000001301, 005000928, 000001302	no

Table III.C-3 Product-Specific Products Data Requirements for End-Use Temephos, Efficacy (see Part IX) (cont'd)

Aquatic Sites	Name of Pest	Are Data Required for this Standard?	Composition and Active Ingredient/ Acre (AI/A)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
Intermittently flooded areas, temporary rain pools, catch basins, standing water, woodland pools, shallow lakes and lake margins, log ponds, sloughs, stagnant water, marshes, tidal waters, swamps	Mosquito larvae	yes	4 lbs emulsifiable concentrate (0.016 to 0.047 lb AI/A)	yes	000001236, 000001245, 000001247, 000001249, 000001317, 000001326, 000001331, 000001347, 000001349, 000001350, 000001351, 000001399, 000004967, 000004968, 005000710	no

Table III.C-3 Product-Specific Products Data Requirements End-Use Temephos, Efficacy (see Part IX) (cont'd)

Pet and Pet Quarters Sites	Name of Pest	Are Data Required for this Standard?	Composition and Active Ingredient/ Acre (AI/A)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
Cats: Direct body application and living quarters	fleas	yes	2% Dust	yes	000001217, 000001219, 000001224, 000001225, 000001226, 000001227, 000001228, 000001234, 005000784, 005000792, 005001005	no
Cats: pets collars	fleas	yes	40.7% Impregnated Material	yes	000001260, 000001261, 000001262, 000001270, 000001271, 000001272, 000001273, 000001274, 000001276, 005000793	no
Dogs: direct body application and living quarters	fleas	yes	2% Dust	yes	000001217, 000001218, 000001224, 000001225, 000001226, 000001227, 000001228, 000001234, 005000784, 005000792, 005001005	no

Table III.C-3 Product-Specific End-Use Products Data Requirements for End-Use Temephos, Efficacy (see Part IX) (cont'd)

Pet and Pet Quarters Sites	Name of Pest	Are Data Required for this Standard?	Composition and Active Ingredient/ Acre (AI/A)	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard.
Dogs: pet collars	fleas	yes	40.7% Impregnated Material	yes	000001260, 000001261, 000001262, 000001268, 000001270, 000001271, 000001272, 000001273, 000001274, 000001275, 000001290, 005000793	no

August, 1981

IV. Product Chemistry

A. Introduction

The Agency published "Proposed Guidelines for Registering Pesticides" which explains the minimum product chemistry requirements for registering pesticide products in the United States (see 43 FR 29696, July 10, 1978). The Agency requires the following information on chemical identity, manufacturing process, active ingredient limits in pesticide products, product analytical methods and data, and physical/chemical properties in order to assess a pesticide's product chemistry.

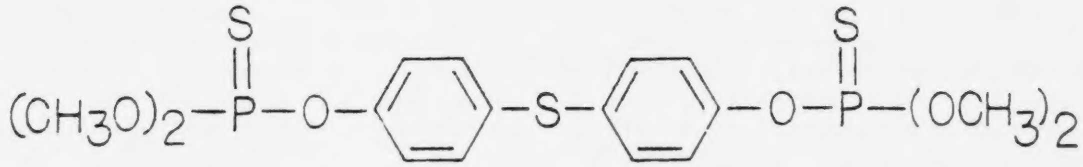
B. Chemical Identity

The Agency requires identifying information including chemical names, product names, and numerical codes of all substances known or assumed to be present in pesticide products. As discussed in Part II.B, the common name accepted for temephos by the American National Standards Institute (ANSI) is O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl phosphorothioate). The empirical formula for temephos is $C_{16}H_{20}O_6P_2S_3$; it has a molecular weight of 466.4; its chemical structure is shown in Figure 1. An alternative chemical name for the compound is O,O,O',O'-tetramethyl O,O'-thiodi-*p*-phenylene phosphorothioate and is also known by such trade names as Abate®, Abathion®, Abat® and Biothion®. The Chemical Abstracts Registry (CAS) number for temephos is 3383-96-8, the American Cyanamid internal code number is 52160 (prefixed by AC-, CL-, or EL-), and the EPA Shaughnessy number is 059001. Thus, the nomenclature of temephos has been adequately defined.

C. Manufacturing Process

A detailed description of the manufacturing process is required because the route by which a pesticide is synthesized determines the nature and amount of potentially toxic impurities. Technical temephos is made by reacting dimethylchlorothiophosphate with an alkali salt of 4,4'-dihydroxyphenyl sulfide [4,4'-thiodiphenol] (Pasarela and Orloski, 1973, MRID #005000638). Detailed information (American Cyanamid Co., 1975?, MRID #000001278 and American Cyanamid Co., 1978, MRID #GS0006001) on technical temephos manufacture is Confidential Business Information and is appropriately safeguarded in Agency files. However, the manufacturing process of technical temephos is not detailed enough to satisfy the Agency's requirements. Data on the composition of the technical product indicate that there are several classes of impurities present and identification of individual compounds within a class is difficult (American Cyanamid Co., 19??, MRID #000003268, and American Cyanamid Co., 1974, MRID #000001216). The impurities exceeding 0.1% of the technical temephos product weight must be determined.

The Agency also needs data on the manufacturing process of the other manufacturing-use products and most end-use products. A process description has been submitted on the temephos-



Empirical Formula:

$C_{16}H_{20}O_6P_2S_3$

Molecular Weight:

466.4

FIG. I

containing flea collars (American Cyanamid Co., 1976, MRID #000001267), but the amounts of starting materials are lacking.

D. Product Analytical Methods and Data

Spectrophotometric and gas chromatographic methods for analysis of temephos in the technical product and in formulations have been published (Pasarela and Orloski, 1973, MRID #005000638). For analysis by ultraviolet spectrophotometry, solid samples are extracted with methylene chloride, the solvent evaporated, and the residue dissolved in a mixture of ethyl acetate and hexane. Liquid samples are dissolved directly in the ethyl acetate-hexane solvent. Samples are cleaned up on silica gel columns, the column eluate evaporated to dryness, and the residue dissolved in methanol. The absorbance of the methanol solution at 274 nanometer (nm) wavelenght is determined and the temephos content determined by comparison to a standard carried through the clean-up procedure.

Precision of the method is claimed to be ± 1.0% for technical temephos, ± 0.7% for 6E emulsifiable concentrates, and ± 0.2% for 1% through 3% granular formulations (Pasarela and Orloski, 1973, MRID #005000638).

For gas-chromatographic analysis of products, liquid samples or methylene chloride extracts of solid samples are diluted with methylene chloride, the solutions cleaned up on columns of acidic alumina, and the column eluate analyzed for temephos on a gas chromatographic column of OV-22® silicone on 60-80 mesh Gas-Chrom Q® equipped with a flame ionization detector. An internal standardization technique is used to determine the content of temephos. Claimed precision for the method when peak areas are determined by electronic integration is ± 1.0% for the technical product, ± 0.7% for 6E emulsifiable concentrates, and ± 0.02% for 1% through 3% granular formulations (Pasarela and Orloski, 1973, MRID #005000638).

For determination of temephos in flea collars, one gram of collar is dissolved in tetrahydrofuran and polymeric material precipitated by addition of hexane. The solution is cleaned up on a silica gel thin-layer chromatography plate, temephos eluted from the plate with methanol, and the concentration of temephos in the methanol solution determined by spectrophotometry (Fiala, 1975, MRID #000001269)

Methods for the determination of active ingredient in temephos containing products have been published, but validation data and results of analysis obtained by these methods have not been submitted.

E. Physical/Chemical Properties

A small amount of data is available on the physical/chemical properties of temephos. Data which are not available but which are required to be submitted are listed in the Tables III.A through C in Part III. All of the following physical/chemical property data were developed by the American Cyanamid Company. The year of publication and Master Record Identification (MRID) numbers are as follows: 19??, #000003264; 1972?, #000001379; 1974?, #000001223; 1974?, #000001222: and 1969, #000001254. Each property listed below has only the MRID number referenced or references are made to the Confidential Statement of Formula (CSF). The following available data for temephos are either for the purified grade, technical grade, or formulated product as noted.

Color: The purified grade is a white crystalline solid (MRID #000001379); the technical grade is a brown viscous liquid (MRID #000001379); and the end-use product, EPA Reg. No. 241-132, is an amber liquid (MRID #000001254).

Odor: End-use product, EPA Reg. No. 241-132, is described as having a "typical aromatic petroleum odor" (MRID #000001254).

Melting Point: Purified grade melts at 30.0°-30.5°C; technical may crystallize below 15°C (MRID #000001379).

Density or Specific Gravity: The specific gravity of technical temephos is 1.3 at 25°C (MRID #000001379). The density of a manufacturing-use product, Abate® 70% concentrate (EPA Reg. No. 241-242), is 1.21 gms/cm^3 (CSF). The density of two end-use products is 1.2 gms/cm^3 (CSF) for a 6E formulation (EPA Reg. No. 241-223) and 1.13 gms/cm^3 for a 4E formulation (EPA Reg. No. 802-495) [MRID #000001379].

Physical State: Purified grade is a crystalline solid and technical grade is a viscous liquid (MRID #000003264). Formulations currently registered are liquids, granules, dusts or impregnated materials (CSF).

Stability: Technical grade appears to be indefinitely stable at room temperature and moderately stable to hydrolysis in contact with aqueous alkali. No hydrolysis was observed at pH 8 at room temperature for several weeks or at pH 11 at 40°C for several hours; hydrolysis at high pH for prolonged periods of time may be expected (MRID #000001379).

Solubility: Technical grade is soluble in water at 25 ppb at 25°C (MRID #000001379); also soluble in the following solvents*: acetonitrile, carbon tetrachloride, chloroform, ether, ethylene dichloride, lower (molecular weight) alkyl ketones, and aromatic hydrocarbons. It is insoluble in hexane and methyl cyclohexane (MRID #000001379).

Storage Stability: The stability of end-use products stored under typical conditions is the basis for over formulation or for assigning expiration dates, and for assessing changes over time of such physical/chemical properties as pH, viscosity, color, odor, and density. The Agency has information on the 25% dust concentrate, EPA Reg. No. 241-235 (MRID #000001223) and the 2% powder, EPA Reg. No. 241-234 (MRID #000001222). However, the storage conditions of these two formulations are not sufficiently detailed.

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* The Agency requires a numerical value for solubility of temephos in organic solvents.

Flammability: Data on flammability determines the type of flammability warnings to be placed on labels of pesticide products. The manufacturing-use product, Abate® 70% concentrate insecticide (EPA Reg. No. 241-242), has a flash point of 84°C T.O.C. (CSF); and the end-use products have a flash point of 43°C T.C.C. and >85°C T.O.C. (CSF), and >80°C T.O.C. (CSF) for Biothion® 6E Insecticide (EPA Reg. No. 241-223) and Abate® 4E Insecticide (EPA Reg. No. 241-132), respectively.

Specific Viscosity: Technical grade (liquid), EPA Reg. No. 241-220, has a viscosity of 3,000 centipoises (cp) at 5°C, 300 cp at 25°C, 180 cp at 40°C, and 30 cp at 80°C (MRID #00001379). The viscosity of the liquid end-use product (EPA Reg. No. 241-132) is approximately 36 cp at 25°C (MRID #000001379).

F. Summary of Data Gaps

Though some information is available to satisfy the Guidelines' requirements on description of manufacturing process, discussion on formation of unintentional ingredients, declaration and certification of ingredient limits, and product analytical methods, additional data are required in all instances for the manufacturing-use and end-use products (see Tables III.B-1 and C-1 for specific-data requirements).

There is little or no information for technical temephos regarding odor, octanol/water partition, pH, solubility in organic solvents, boiling point*, vapor pressure, and product identity and disclosure of ingredients.

There is little or no information for temephos manufacturing-use products regarding density or specific gravity, pH, storage stability, flammability (liquid), oxidizing or reducing action, explosiveness, miscibility (liquid), viscosity coefficient (liquids), and corrosion characteristics. There is also little or no information for temephos end-use products regarding color, odor, density or specific gravity, pH, storage stability, flammibility (liquid), oxidizing or reduction action**, explosiveness**, miscibility (liquids), viscosity coefficient (liquids), and corrosion characteristics**.

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* Data may be submitted indicating that the boiling point cannot be determined.

** Based on the Confidetial Statement of Formula, the data are not required for the currently registered impregnated materials.

V. Environmental Fate

A. Use Summary

Temephos is primarily a larvicide for use against the larval stage of mosquitoes, gnats, and biting midges (punkies and sand flies). The only registered food use (Federal Registration) is for the control of thrips on oranges and tangerines in Arizona and California. It is also registered for control of fleas on cats and dogs, and in their living quarters.

The major areas of application for temephos are considered aquatic such as intermittently flood areas, marshes, lake margins, ponds, pools, sloughs, standing water and sandy beaches.

The percent of temephos in the various federally registered end-use formulations are as follows: emulsifiable concentrates: 43, 45.2, 48.5, 50.3 and 60%; granular formulations: 1, 2 and 5% temephos; dust formulation: 2%; and impregnation in pet collar material: 40.7%.

The granular and emulsifiable concentrate formulations are used predominately for the control of mosquitoes, gnats and biting midges. The rates of application range from 0.05 to 0.5 lb of active ingredient (ai)/acre for the granular form and from 0.016 to 0.047 lb ai/acre for the emulsifiable concentrate. The granular formulations contain, by weight, 1-5% of the active ingredient, whereas the emulsifiable concentrate contains 4 lbs of the active ingredient per gallon.

Higher application rates are registered for polluted aquatic sites and those sites that contain increased levels of organic content. The dust formulations and the impregnated pet collar have an unspecified rate of application. The emulsifiable concentrate registrated for use on orange and tangerine trees has a 1.0 lb ai/acre aerial or ground application rate.

The Agency estimates that the total usage of temephos as an active ingredient is 100,000-200,000 lbs, annually. The quantity used for non-aquatic site treatment (e.g., food use), which currently is exported, is quite minor, probably less than 2%.

B. Environmental Fate Profile

The available data are insufficient to fully assess the environmental fate of temephos [O,O'-(thiodi-4,1-phenylene)bis(O,O-dimethyl phosphorothioate)].

1. Hydrolysis

Available preliminary data from a microbial degradation study (Daorai and Menzer, 1977, MRID #005000796) on the hydrolysis of radiolabeled temephos indicate a degradation rate of about 10%

after 10 days in distilled water (pH near neutral), resulting in the following five degradation products:

1) O,O,O',O'-tetramethyl O,O'-sulfinyldi-p-phenylene phosphorothioate (S-SO-S);

2) O-(p-(p-hydroxyphenylthio)phenyl) O,O-dimethyl ester with O',O'-dimethyl phosphate (S-S-O);

3) O-(p-(p-hydroxyphenylsulfonyl)phenyl) O,O-dimethyl ester with O',O'-dimethyl phoshate (S-SO_2-O);

4) O-(p-(p-hydroxyphenylthio)phenyl) O,O-dimethyl phosphorothioate (S-S-OH); and

5) O,O,O',O'-tetramethyl O,O'-thio-p-phenylene phosphate (O-S-O).

The first degradation product listed was predominant. These data indicate a relatively slow rate of hydrolysis for temephos. However, the data that are available on hydrolysis is considered insufficient because the Daoria and Menzer findings (1977, MRID #005000796) are not conclusive.

2. Microbiological - Effects of Microbes on Pesticides

Evidence regarding the bacterial degradation of temephos (1% Abate®) indicated that previous soil enrichment with temephos may increase the degradation rate of the compound to seven different products. Daorai and Menzer (1977, MRID #005000796) found that soil containing 1% temephos, plus an unidentified bacterium (possibly a Pseudomonas) previously cultured in the presence of temephos, resulted in 47% degradation of the applied compound (1% Abate®) to unidentified water-soluble metabolites of temephos in 10 days, whereas the presence of a second bacterium not previously cultured in the presence of temephos, produced only 28% degradation of the compound to the water-soluble metabolites over the same period of time. Five of the seven degradation products from both bacterial cultures were the same as those formed by hydrolysis. Two additional degradation products formed by both bacterial cultures were unidentified. This study provided some preliminary information on the microbial degradation of temephos by two unidentified bacterial species; however, further studies with a series of microbes indigenous to temephos treatment sites are necessary before an adequate assessment of microbial metabolism of temephos can be made.

3. Anaerobic and Aerobic Aquatic Metabolism

Temephos was degraded relatively rapidly in samples of outdoor waters (Drevenkor et al., 1977, MRID #005000718). According to preliminary data, only 40% and 57% of the temephos added at about 0.7 ppm as a granular formulation remained after 26 days in polluted brook and puddle water, respectively. Soluble temephos was not detected in the puddle water samples at the end of the test period, and only about 40% of the temephos detected in the brook water at the end of testing (26 days) was in the soluble state. This study provides only preliminary information on aquatic metabolism since metabolites were not analyzed and some minor problems may have been caused by interfering substances.

4. Microbiological - Effects of Pesticides on Microbes

Preliminary data indicate that the effect of temephos on microbial populations is generally slight. Bacterial populations in waste water exposed to an unspecified formulation of temephos at 1 ppm exhibited minimal effects over a 48-hour test period. At higher concentrations (1,000-50,000 ppm), temephos decreased bacterial populations 49-87% after 24 hours (Steelman et al., 1967, MRID #005001102). Temephos concentrations of 20 ppb and 500 ppb increased the rate of nitrogen fixation in mixed plankton cultures (94% of the culture consisted of the blue-green alga Aphanizome flos-aquae) to about 160% and 390%, respectively above controls (Wurtsbaugh and Appersen, 1978, MRID #005011182). Other data demonstrated that temephos at 2.5 ppm in Danube River water within 24 hours of exposure had a slight inhibitory effect (10-30% growth inhibition) on major phytoplankton populations, including green algae, diatoms, and euglenoids. Temephos at higher concentrations resulted in greater inhibitions. Conversely, temephos (1% in sand granules) at 2.5 ppm caused a 100% increase in blue-green algal populations (Tevan and Lang, 1975, MRID #005003734). These studies provided partial information concerning the effect of temephos on nitrogen fixation by blue-green algae and the effect of temephos on populations of aquatic algae. Further studies are needed for temephos that use other soil microorganisms and address other parameters, including oxygen consumption, carbon dioxide evolution, nitrogen cycle reactions and enzyme activities. The Agency also recommends that additional data be acquired on the effects of temephos at higher concentrations (above 2.5 ppm) on nontarget algae populations (eucaryotic algae) since the available data and the use patterns indicate that temephos may have an adverse impact on these organisms, which constitute the majority of primary producers in aquatic environments.

5. Field Dissipation - Aquatic

Preliminary data from one study (Henry et al., 1971, MRID #005000794) indicated that temephos (technical grade) concentrations decreased quickly from an initial level of 0.1 ppm to steady-state concentrations of 0.02-0.04 ppm within 48 hours in a micro-marsh at temperatures of 10-35°C. In another study (Vrochinskii, 1976, MRID #005003887), the half-life of an unspecified formulation of temephos applied at about 3.5 ppm to a model reservoir (18-20°C, pH 7.4 to pH 8, dissolved O_2 at about 6-8 ppm) was 9 days. By 113 days, 95% of the applied temephos had dissipated. In both studies, the degradation products were not identified but indicated a moderately low degree of persistence for parent temephos in the aquatic environment.

6. Fish Accumulation

Preliminary data indicated that temephos (50% emulsifiable concentrate) accumulated in Indopacific milkfish (Chanos chanos) exposed to the compound at about 0.35 ppm had a relatively low bioaccumulation factor of approximately 2 over an unspecified time period (Tsai, 1978, MRID #005000978). Rapid depuration occurred as the temephos residue level declined over a 14-day period, from about 0.7 ppm to about 0.02 ppm, in both whole and edible fish tissues.

In summary, temephos is hydrolized relatively slowly; however, limited data suggest in aquatic environments, temephos degrades rapidly to at least seven different products, five known and two unidentified. The environmental fate of these products is unknown. This pesticide generally has limited effects on bacterial populations, but may have an adverse impact on eucaryotic algae. Growth and nitrogen fixation is stimulated by temephos in some blue-green algae exposed at low concentrations. In a static flow study, temephos exhibited a low accumulation potential and rapid depuration in fish. Additional studies are required to measure the effects of temephos on fish in a flow through environment.

C. Exposure Profile

1. Introduction

Granular (G) and emulsifiable concentrate (EC) formulations of temephos are registered for control of aquatic larvae (mosquitoes, sand flies, midges, gnats, etc.) at a variety of sites (sandy beaches, catch basins, lakes, marshes, ponds, etc.). The G and EC formulations are applied at rates ranging from 0.05 to 0.5 lb ai/acre and from 0.016 to 0.047 lb ai/acre, respectively. These formulations are primarily applied by aircraft, although hand sprayers, mechanical ground sprayers, broadcast and ultra low volume (ULV) ground applications are also used.

A dust formulation and temephos in impregnated material (flea collars) are registered for control of fleas on dogs and cats (the dust formulation is also used in pet living quarters and bedding).

2. All Formulations (except impregnated materials)

A comprehensive exposure profile cannot be generated at the present time (August, 1981) because of the scarcity of data. However, from the data which are available, the following profile can be developed:

> The principal region of exposure is expected to be the northeastern quarter of the United States and Florida where the greatest use of temephos occurs. As with most pesticides, the greatest human exposure will probably be to workers engaged in mixing, loading, and working in treatment operations. However, quantitative

data are not available to estimate the degree of such occupational exposure nor to accidental exposures, i.e., the public which may be within or surrounding the area of application, or human exposures resulting from the domestic use. The potential exposure by inhalation of volatilized temephos cannot be assessed due to the lack of vapor pressure and volatility data on the manufacturing-use product or formulations. Similarly, the lack of soil mobility data prevents an assessment of the potential for human dietary exposure through ground water contamination. Degradation of temephos by soil bacteria has been demonstrated, but the unknown environmental fate of the temephos degradation products prevents an adequate determination of how important this degradation is in eliminating use-associated hazards. Field dissipation data do suggest a slight persistence of temephos in the aquatic environment.

a. Granular Formulations

Granular formulations of temephos are applied primarily via aircraft. The potential for human exposure (especially respiratory and ocular) during loading operations is recognized, although available information indicates that such exposure is minimized by the use of protective clothing and a respirator or surgical mask during this operation*. The potential for pilot exposure during application is minimized by positive air flow ventilated aircraft cabins and by closed insecticide delivery systems. Drift from aerial application of these formulations is not considered an important mode of exposure for persons, livestock, and wildlife outside the application site due to the weight of the granules.

Applicator exposure during ground applications may be higher than during aerial applications where, as discussed above, the pilot is protected from the insecticide. However, the reported use of rubber boots, gloves, coveralls, and respirators by ground applicators can reduce exposure during loading and application*.

The potential exposure of nontarget organisms, especially wildlife, through contact with treated surface waters must also be considered, although preliminary environmetnal fate data indicate that such exposure might be limited by the dissipation of temephos in aquatic systems. The aquatic field dissipation of temephos has been demonstrated to vary between a half-life of 9 days in a model reservoir to less than 48 hours in micro-marsh ponds.

The labeling for these products recommends "avoid contact with eyes, skin and clothing" and "avoid breathing spray mist or dust."

b. Emulsifiable Concentrate Formulations

Exposures resulting from the use of emulsifiable concentrates of temephos in aquatic areas are expected to be similar to those discussed previously for granular formulations. Although a potential for dermal exposure via splashing of the EC formulations during dilution and tank mix operations is recognized which could be further reduced by use of a closed transfer system, such exposure would be minimized by the use of protective equipment described previously. The potential for spray drift from the use of emulsifiable concentrate formulations is especially high because these formulations are commonly applied from aircraft as ULV sprays.

c. Impregnated Materials

Little exposure to humans is expected from such formulations. Exposure that does occur is likely to be dermal in nature, resulting from handling flea collars. No exposure to wildlife or livestock is expected from these formulations.

d. Dust Formulations

Little exposure to humans, wildlife, or livestock is expected to result from using these formulations for controlling fleas on cats and dogs, and their living quarters.

D. Summary of Data Gaps

The data gaps that are to be filled are hydrolysis, photodegradation, aerobic aquatic metabolism, fish accumulation, leaching, adsorption/desorption, water dispersal, terrestrial field dissipation (tree fruit and nut crop use), aquatic field dissipation (aquatic noncrop use), terrestrial/aquatic (forest field dissipation), accumulation in irrigated crops, special studies (accumulation in aquatic noncrop uses), aerobic soil metabolism, and anaerobic aquatic metabolism.

There are data gaps relating to disposal and storage, microbial metabolism and activated sludge. However, pending review and modification of the testing protocol, it is currently not necessary to satisfy these data gaps. Further testing details are in Part III.

VI. Toxicology

A. Toxicology Profile: Technical Temephos

Temephos is an organophosphorus pesticide. Low doses of temephos would be expected to inhibit cholinesterase activity without necessarily causing acute signs. In vivo, temephos has been shown to inhibit cholinesterase activity. In rats, subchronic oral doses as low as 6 ppm resulted in depressed erythrocyte cholinesterase activity (Levinskas, 1965, MRID #000001239). In dogs, subchronic oral doses of 700/500 ppm caused depressed erythrocyte, brain, and plasma cholinesterase activities (Hutchinson and Levinskas, 1965, MRID #000001356). Subchronic oral dosing with temephos caused no effect on survival, food consumption, or tissue and organ histopathology in rats given up to 350 ppm in the diet, and dogs given up to 700/500 ppm in the diet for 90 days (Levinskas, 1965, MRID #000001239 and Hutchinson and Levinskas, 1965, MRID #000001240). Weight gain was reduced in rats given 350 ppm for 90 days. Cholinesterase activity was depressed after subchronic oral dosing. In another subchronic oral study (American Cyanamid Co., 1964, MRID #000001252), male rats were fed diets containing 0, 250, 500, and 1000 ppm (0, 0.025, 0.05, and 0.1%) technical temephos for 30 days. The No Observable Effect Level (NOEL) for systemic effects was 250 ppm and the Lowest Effect Level (LEL) was 500 ppm; the effect being weight gain depression. Cholinesterase depression (i.e., brain, plasma, and erythrocyte) was noted in all dose groups.

The relatively high acute oral LD_{50} (0.77-13.0 g/kg) of technical temephos in rats suggests a low acute hazard in humans (American Cyanamid Co., 1966?, MRID #000001354; Gaines et al., 1967, MRID #000001368; Gaines, 1969, MRID #005000974 and McNerney and Levinskas, 1967, MRID #000001365). The large range in LD_{50} values might be attributed to differences in sensitivity of the strains of rats tested. Signs of toxicity in rats were characteristic of organophosphate intoxication (i.e., tremors, salivation, diarrhea, tearing, depression, and weakness).

A moderate dermal hazard in humans is suggested by the relatively low acute dermal LD_{50} in rabbits (0.97 g/kg to greater than 4 g/kg) [American Cyanamid Co., 1966?, MRID #000001354 and Gaines, 1969, MRID #005000974]. In another study which provided supplemental information using male rabbits, the LD_{50} was estimated to be 1.02 g/kg (American Cyanamid Co., 1964, MRID #000001252). No tests of primary dermal irritation or an adequate subchronic dermal studies were available on the technical temephos.

In an acute inhalation study, albino CF Nelson rats (six males) were exposed to air saturated with technical temephos (concentration unspecified) for 8-hours (American Cyanamid Co., 1964, MRID #000001252). Deaths did not occur and toxic signs were not noticed; suggesting that technical temephos has a low acute inhalation toxicity potential. However, until data aresubmitted to support the statement that the test concentration was at the saturation level, additional testing will be required.

Temephos has a very low potential for eye irritation in humans based on a test in rabbits. Instillation of this material into the conjuctival sac of rabbits resulted in no eye irritation (American Cyanamid Co., 1974, MRID #000001352).

In Sprague-Dawley rats, dietary administration of technical temephos at doses of 10, 100, and 300 ppm for 2 years had no adverse effects; however cholinesterase activities were not measured (Underwood, 1977, MRID #000001386). This study can be used to assess the chronic and oncogenic potential of temephos. An oncogenic study using mice will be required on the technical product (see Table III.A-3 in Part III for Toxicology).

There are no adequate studies available on the teratogenic and mutagenic effects of temephos. In a reproduction study, no treatment-related effects occurred in the reproductive capacity of rats given dosages of 25 ppm or 125 ppm temephos. Furthermore, no effects were noted in the offspring of these rats (McNerney _et_ _al_., 1968, MRID #000001388).

Metabolism of temephos is relatively rapid after oral dosing. In rats and guinea pigs, about 95% of a single oral dose of temephos was eliminated by fecal and urinary routes within 96 hours. The average half-life of temephos was reported as 10 hours in rat blood (Blinn, 1966, MRID #000001376 and Blinn, 1969, MRID #005000858) and the residues of temephos in tissue were relatively low; adipose tissue contained the highest levels (1-2 ppm). Metabolites identified in urine and feces were 4,4'-thiodiphenol, and to a lesser extent, 4,4'-sulfinyldiphenol, either free or as glucuronide or sulfate conjugates (Blinn, 1969, MRID #005000858).

When temephos was applied as a single dermal dose to lactating goats, approximately 33% of the absorbed dose was excreted in urine, 50% was excreted in the feces, and 12-15% was present as tissue residues at 14 days (Chiu and Eisner, 1975, MRID #000001343). The metabolites identified in the urine and feces of goats (either free or as conjugates) were 4,4'-sulfinyldiphenol and temephos sulfoxide which were also indentified in the rat. In addition, temephos sulfone and monooxon were found in feces. Residues of about 0.3 ppm were found in fat. Shafik (1970, MRID #005000806) demonstrated that a temephos metabolite 4,4'-thiodiphenol reached its peak level in rats after a 3 day daily dosing of 9.6 mg/Abate®. The metabolite peaked at 300 ug/day and then dropped to 10 ug/day after 14 days.

B. Toxicology Profile: Manufacturing-Use Temephos

Using a 25% temephos dust concentrate, very low acute oral hazard and a low acute dermal hazard are expected. This is because the oral LD$_{50}$ in male rats is 6.20 g/kg body weight and the dermal LD$_{50}$ in male rabbits is greater than 5 g/kg (Fischer, 1974, MRID #000001307).

Applying a 70% concentrate of Abate®, the acute oral LD_{50} in male rats was 2.03 g/kg body weight and the dermal LD_{50} in male rabbits was 1.89 g/kg body weight (American Cyanamid Co., 1974, MRID #000001352).

The 25% temephos dust concentrate is expected to have a very low eye irritation potential in humans because instillation of this material in rabbit eyes resulted in only mild conjunctival irritation at 24 hours (Fischer, 1974, MRID #000001307). The primary eye irritation test using a 70% concentrate on rabbits showed negative results (American Cyanamid Co., 1974, MRID #00001352).

In a primary dermal irritation study, mild to moderate erythema was observed 72 hours after a 70% concentrate formulated intermediate was applied to abraded rabbit skin (American Cyanamid Co., 1974, MRID #000001352). This study is also sufficient to support the toxicity of the 25% dust concentrate.

C. Toxicology Profile: End-Use Temephos

1. Emulsifiable Concentrate

Low acute oral toxicity and low acute dermal toxicity are expected in humans for Abate® mosquito larvicide (one gallon contains 4 lbs of 51.5% temephos) based on the relatively high oral LD_{50} in rats (3.08-3.53 ml/kg) and dermal LD_{50} in rabbits (1.77-2.03 ml/kg) [American Cyanamid Co., 1966?, MRID #000001354].

Acute oral LD_{50} of Biothion® 6E (containing 69.2% temephos by weight or 60% active ingredient) in male rats (1.40 g/kg) suggests a low acute oral hazard potential in humans. Similarly, the acute dermal LD_{50} in male rabbits (5.60 g/kg) indicates low dermal hazard (American Cyanamid Co., 1971; MRID #000001353). Placing Biothion® 6E in the conjunctival sac of rabbits caused mild to moderate conjunctival irritation and mild corneal irritation (American Cyanamid Co., 1971, MRID #000001353). However, this study is not sufficient to classify the toxicity of the EC formulations because the observation time for development of corneal opacity in the test animals did not exceed 72 hours.

In an acute inhalation study using the 4 lbs/gallon emulsifiable concentrate, Wistar rats were exposed to 2.68 mg/liter (nominal concentration) for 1 hour and were observed for 7 hours following exposure (American Cyanamid Co., 1966?, MRID #000001354). The animals did not die but they did exhibit annoyance and discomfort. This study demonstrated that the 4 lbs/gallons EC has a low acute inhalation toxicity potential.

In a primary dermal irritation study, application of 0.5 ml of the 4 lbs/gallons emulsifiable concentrate on intact and abraded rabbit skin resulted in moderate to severe erythema and edema which persisted at the 72 hour reading (American Cyanamid Co., 1966?, MRID #00001354). This study indicates that the

4 lbs/gallon EC formulations cause moderate to severe dermal irritation.

2. Dust Formulation

Using a 2% Abate® dusting powder, the oral LD_{50} in male rats was greater than 5 g/kg body weight and using a 2.44% (by weight) temephos powder, the oral LD_{50} in male rats was greater than 10 g/kg body weight (American Cyanamid Co., 1971, MRID #000001308 and American Cyanamid Co., 1973, MRID #000001233). Both dusts tested on male rabbits showed a dermal LD_{50} greater than 5 g/kg body weight.

A test in rabbits using the 2% dusting powder revealed no eye irritation, and tests using the 2.44% (by weight) formulation revealed only mild conjunctival irritation after 4 hours. These dusts were also tested in an acute dermal study on intact and abraded skin of rabbits and showed only mild dermal irritation (American Cyanamid Co., 1971, MRID #000001308 and American Cyanamid Co., 1973, MRID #000001233). In the primary dermal irritation study, application of 0.5 grams of an aqueous paste of a 2% dust resulted in mild erythema at 24 through 72 hours; indicating a very low potential for dermal irritation (American Cyanamid Co., 1973, MRID #000001233).

Regarding the subchronic dermal toxicity test, dogs, using 2% temephos powder with a dosage of 80 mg/kg body weight once a week for 3 weeks, or 20 mg/kg body weight for five days a week for three weeks, resulted in no adverse effects including no effects on cholinesterase activity and growth. Cats dosed with the same powder with a dosage of 80 mg powder per kilo of body weight one or five times a week for three weeks showed some inhibition of plasma and erythrocyte cholinesterase activity. In these tests, however, sample size were quite limited and changes in various parameters (e.g., other toxic effects) might not have been detected (Wang et al., 1974, MRID #000001232).

In humans, single-dose dusting with a 2% formulation of temephos in pyrax powder did not result in depresson of whole blood cholinesterase values (Steinberg et al., 1970, MRID #005001274). Patch tests with this formulation indicated no evidence of skin irritation or sensitization in humans (Steinberg et al., 1970, MRID #005001984). Sleeve-tests with 1% or 2% temephos in pyrophyllite powder resulted in no ill effects (Cole et al., 1971, MRID #000001312). Ingestion of increasing doses of temephos (2-256 mg/day) over four weeks or daily doses of 64 mg/day for four weeks did not result in alterations in red blood cell or plasma cholinesterase activity or in clinical symptoms (Laws, 1975, MRID #000001375).

3. Granular Formulations

No toxicity data were available on granular formulations containing temephos; however, based on the similarities in the composition of dust and granular formulations, as indicated by the Confidential Statements of Formulae, the studies cited for the dust formulation can be used to support the registrations of the granular formulations.

4. Impregnated Materials

No toxicity data were available on dog and cat flea collars impregnated with temephos. Since the temephos is impregnated into the material and inhalation and dermal sensitization data will be required on the technical grade of active ingredient, the Agency will only require a special impregnated material study (see Table III.C-2.a for study requirements). This study must include an adequate cholinesterase analysis of the animals at risk (i.e., cat and dog). Also, based on the results of the dermal sensitization study required for the technical grade of active ingredient, additional test protocols may be developed, especially in the area of child safety requirements.

D. Human Hazard Assessment

Exposure to temephos can be experienced by the dermal, inhalation or dietary routes. It is difficult to assess the degree of exposure to temephos by inhalation or by ground water contamination, due to insufficient environmental chemistry data.

1. Technical Temephos

Temephos is an organophosphorus pesticide which at low doses inhibits cholinesterase activity in animals without necessarily causing symptoms of acute toxicity. Technical grade temephos exhibits low acute oral and dermal toxicity to animals and it's potential for eye irritation is very low based on animal data. Weight gain and cholinesterase activity were depressed after subchronic dosing of rats (350 ppm in the diet, 90 days) and dogs (700/500 ppm). No effects on reproduction were seen when rats were given up to 125 ppm temephos in their diet. No chronic or oncogenic effects were seen when rats were fed up to 300 ppm temephos. Metabolism studies of temephos indicated that its half-life was about 10 hours in rat blood. Tissue residues were relatively low; adipose tissue had the highest level.

2. Manufacturing-use Products

Based on animal studies, a very low acute oral and a low acute dermal hazard is expected for humans. Based on eye irritation tests in rabbits, the Agency concludes that when results are extrapolated to humans, the eye irritation is expected to be low.

3. End-Use Products

a. Emulsifiable Concentrate (EC) Formulations

The acute oral and dermal toxicity of Abate® mosquito larvicide (51.5% temephos) is expected to be low, based on animal data. This formulation is expected to be moderately irritating to human eyes, and to be a moderate to severe dermal irritant.

Biothion® 6E (69.2% temephos by weight) is similar to Abate® mosquito larvicide in its acute oral toxicity and dermal toxicity effects. Its ability to cause eye irritation is similar to Abate® mosquito larvicide (51.5% temephos). Dermal exposure to humans is possible via splashing during dilution and the tank mixing of these formulations. The acute inhalation test provided information that the emulsifiable concentrate (EC) formulation has a low inhalation toxicity potential. The primary dermal irritation test revealed a moderate to severe dermal irritation potential.

b. Dust Formulations

Based on animal toxicity studies using 2% temephos powder, it is expected that for humans, temephos has the potential to cause very low levels of acute oral toxicity, acute dermal toxicity, primary dermal irritation and eye irritation.

Subchronic dermal dosing using dogs showed no effect, whereas cats showed some inhibition of cholinesterase activity. When temephos was used on humans for single dose dusting, patch tests, sleeve-tests and oral ingestion, no effects were evident.

In a study pertaining to the application of a 2% Abate®/98% pyrax dust formulation for lice control, it was suggested that the operator of the dusting equipment use some form of respiratory protection to minimize exposure. However, this is an empirical evaluation and not based on any quantitative risk/benefit analysis.

d. Granular Formulations

Granular formulations are applied by using aircraft, thus exposure to people outside the application site due to spray drift may be a concern. In general, applicator exposure during ground applications could be reduced by use of protective clothing and respirators. However, this is an empirical evaluation and not based on any quantitative risk/benefit analysis.

e. Impregnated Material

Because of the data gap for the impregnated materials, the Agency cannot adequately assess the hazard potential to domestic animals and humans from this formulation. However, information available on the technical and emulsifiable concentrate formulations of temephos indicate that a low hazard to domestic animals and humans is expected.

E. Summary of Data Gaps

The generic data gaps for technical grade temephos are acute inhalation toxicity, dermal sensitization, acute delayed neurotoxicity, teratogenicity, mutagenicity and oncogenicity (mouse).

Oncogenicity (in the mouse), teratogenicity, and mutagenicity tests are required because temephos is registered for use on food crops. Some of these studies (see Table III.A-3) are also required for the domestic uses of temephos (i.e., for direct application on cats, dogs, and in their living quarters; dogs' and cats' flea collars). The data required for the food crop use is also required to maintain the established tolerance. If these studies are not provided to maintain the tolerance, the Agency will implement procedures under FIFRA Section 180.001 and Food and Drug Cosmetic Act (FDCA) Section 408(e) to revoke the temephos-established tolerance.

The data gap for end-use temephos products are the 21-day dermal sensitization test for the dust formulation and an impregnated material study for the flea collar products on the animals at risks (i.e., cat and dog). In addition to the dermal sensizition test being conducted on the technical grade of active ingredient, test protocols may also be developed, especially in the area of child safety requirements. The data gap for the emulsifiable concentrate is the primary eye irritation test.

VII. Residue Chemistry

A. Introduction

Temephos is an insecticide with registered uses on 1) dogs, cats, and in their living quarters for control of fleas; 2) orange and tangerine trees to combat thrips, and 3) aquatic sites to control larvae of mosquitoes, "gnats", and certain biting midges.

Foliar treatment with a 60% emulsifiable concentrate of temephos is used for control of thrips on orange and tangerine trees. Following harvest of mature fruit, the formulation is applied at one pound per acre at prebloom or at petal fall, but not during bloom. The formulation may also be applied to nonbearing trees. The formulation is diluted in 15 to 20 gallons of water per acre for aerial application and 200 gallons per acre for ground application. There is no specified frequency of application on the label and the use of temephos on citrus is limited to Arizona and California. With the exception of the use on citrus, the above uses of temephos are not food uses; however, the likelihood exists that application of temephos to aquatic sites could result in contamination of drinking water.

B. Metabolism of Temephos in Plants

Whenever a pesticide is proposed for use on agricultural crops, the Agency requires data on the fate of the pesticide in plants.

Data from a single study indicated that a variety of degradation products of temephos are formed in bean plants (Blinn, 1966, MRID #000001377). In this study, tritiated temephos, with the label ortho to the sulfide linkage, was applied to the primary leaves of three-week old lima bean plants. The plants were grown in a greenhouse and sampled 10, 21, 28 days after treatment. Treated leaves and non-treated plant parts were analyzed separately for metabolites or degradation products.

Total radioactivity on treated leaves remained constant throughout the test period; 94.9, 84.4, and 96.5% of the applied dose were recovered 10, 21, and 28 days respectively after treatment. Most of the radioactivity on treated leaves was methanol extractable; less than 4% was not extracted from the 28 day sample. Only traces of radioactivity were found in treated plant tissue indicating little or no migration from treated areas.

The distribution of temephos degradation products with time is shown in Table VII.A (Blinn, 1966, MRID #000001377). Fraction A contained temephos sulfone and the symmetrical dioxygen analog of temephos. Fraction B contained water soluble conjugates. Hydrolysis products of mixture B contained 4,4'-thiodiphenol and the sulfinyl and sulfonyl derivatives of 4,4'-thiodiphenol. The mono-oxygen analog of temephos sulfone was found in very small amounts.

TABLE VII.A. The Distribution of Temephos Degradation Products in Bean Leaves[a].

	% OF APPLIED DOSE/DAYS AFTER APPLICATION		
Residue	10	21	28
Temephos	85.5	67.3	71.5
Temephos sulfoxide	8.3	4.9	4.3
Fraction A	----	1.1	0.6
Fraction B	----	8.2	16.7

a. Blinn, 1966 (MRID #000001377).

The studies concerning temephos metabolism in plants cannot be considered adequate for the fate of temephos in plants; hence, further studies on degradation of the compound in other plants, uptake from soil, and fate of temephos under actual field conditions must be undertaken.

C. Metabolism of Temephos in Animals

When use of a pesticide on agricultural crops results in residues in products for animal feed, or when a pesticide is applied to food animals, the Agency requires data on the fate of the pesticide in food animals.

Data from a feeding study indicate that temephos and its sulfoxide are interconvertible in animals. The sulfoxide was found in milk of cows fed 20 ppm temephos, and temephos was present in milk of cows fed 5 ppm of the sulfoxide (American Cyanamid Co., 1971?, MRID #000001403).

The sulfoxide was detected in fat and kidney of cattle as a result of dermal application of 0.1% temephos emulsion. Temephos and the sulfoxide were both highest in fat (Manuel, 1975, MRID #000001344).

Chiu and Eisner (1975, MRID #000001343) sprayed three lactating goats with a ^{14}C-temephos formulation, and the goats were sacrificed 2, 7, and 14 days after treatment. The distribution of residues in the treated animals is shown in Table VII.B. The distribution of residues in solid tissues, expressed in ppm, is shown in Table VII.C. Residues in leg muscle, brain, and blood were at or below the sensitivity of the analytical method (0.01 ppm). The tissues of the goat sacrificed on day 14 were analyzed for metabolites of temephos. Residues are tabulated in Table VII.D. Other metabolites found in small amounts include: 4,4'-sulfinyldiphenol; 4,4'-sulfonyldiphenol; glycosides of the sulfinyl- and sulfonyldiphenols, and of 4,4'-thiodiphenol; and mono- and dioxygen analogs of temephos, temephos sulfoxide, and temephos sulfone.

The data on metabolism of temephos in animals are considered adequate to support the current uses of temephos. Current analytical methods for residues of temephos in animals are capable of measuring temephos, temephos sulfoxide, and temephos sulfone.

D. Analytical Methods

A method for the determination of temephos in water, oysters, rice grain, rice foliage (Blinn and Pasarela, 1966, MRID #005000857), and in cottonseed (American Cyanamid Co., 1966, MRID #000001363) has been submitted to the Agency. Samples are extracted with organic solvents, cleaned up on Florisil columns, and hydrolyzed to liberate 4,4'-thiodiphenol, which is then determined colorimetrically. The method is limited because it cannot determine temephos metabolites.

TABLE VII.B. The Distribution of Temephos Residues in Treated Lactating Goats[a].

	% INITIAL DOSE RECOVERED (mg)		
	DAY OF SACRIFICE		
Sample	2	7	14
Hair, extracted	3.10	8.60	18.70
Hide, extracted	46.80	51.70	45.20
Urine	0.80	2.70	3.70
Feces	0.02	3.00	5.60
Milk	0.05	0.05	0.20
Blood	0.05	0.03	0.04
Intestinal Wash	0.30	0.05	0.06
Rumen Content	<0.01	<0.01	<0.01
Solid Tissues	1.70	1.40	2.10
Total Recovery	52.70	67.40	75.50
Initial Dose	141 mg	123 mg	123 mg

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a. Chiu and Eisner, 1975 (MRID #000001343).

TABLE VII.C. The Distribution of Temephos Residues in Solid Tissues from Treated Lactating Goats[a].

	PPM (EXPRESSED AS TEMEPHOS)		
	DAYS AFTER TREATMENT		
TISSUE	2	7	14
Back fat	0.35	0.28	0.29
Omental fat	0.06	0.38	0.36
Liver	0.05	0.04	0.06
Kidney	0.06	0.06	0.03
Heart	0.04	0.07	0.07
Tenderloin muscle	0.05	0.02	0.05

a. Chiu and Eisner, 1975 (MRID #000001343).

TABLE VII.D. The Distribution of Temephos Metabolites in Tissues of a Treated Goat Sacrificed on Day 14[a].

TISSUE	% OF EXTRACTABLE RADIOACTIVITY		
	TEMEPHOS	SULFOXIDE	SULFONE
Hair	68	6.6	0.6
Hide	67	1.6	1.5
Back fat	74	18	----
Omental fat	3	76	10
Milk	5	75	15
Liver	-	39	45
Feces	5	20	10

a. Chiu and Eisner, 1975 (MRID #000001343).

A gas-liquid chromatographic (GLC) method for determination of residues in a variety of samples has been published by Pasarela and Orloski (1973, MRID #005000638). This method has been validated for a wide variety of samples including pasture grass, alfalfa, citrus, broccoli, lettuce, snapbeans, carrots, peanuts, cottonseed, milk, cattle tissues, shrimp, oysters, crabs, fish, and water. Results from 162 samples simultaneously fortified with temephos and sulfoxide at 0.0001 ppm to 5 ppm, indicated that 1) temephos recovery averaged 87% with individual values varying from 55% to 129% and 2) recovery of temephos sulfoxide averaged 88% with values varying from 36% to 129%.

Validation data for the GLC method for various crops are also reported in other studies; alfalfa (Devine, 1969, MRID #000001382), cottonseed (Higham, 1969, MRID #000001297), citrus (Manuel and Devine, 1970, MRID #000001402), cattle tissues (Manuel, 1975, MRID #000001344; Orloski, 1969, MRID #000001392), and milk (American Cyanamid Company, 1971, MRID #000001403).

The claimed sensitivity of the GLC method for most crops is 0.05 ppm, each, for temephos and it sulfoxide; however, control values as high as 0.25 ppm for temephos and 0.44 ppm sulfoxide have been reported (Devine, 1969, MRID #000001382). The method has been tested on cottonseed in two Food and Drug Administration laboratories: successfully in one laboratory (Zee, 1971, MRID #GS0006002), and unsuccessfully in the other (Gibson, 1970, MRID #GS0006003).

Of the temephos methods available, the GLC method of Pasarela and Orloski (1973. MRID #005000638) is satisfactory for obtaining residue data. However, the method determines only temephos and temephos sulfoxide, whereas metabolism data show that temephos sulfone and other degradation products are often minor components of the residue. If these minor residues are found to be toxicologically significant, new methods or modifications to existing methods will be required for their analysis. No analytical method for temephos has been published in the Pesticide Analytical Manual (PAM).

E. Residues in Plants

Whenever a pesticide is proposed for use on an agricultural crop, the Agency requires data on the amount of residue on the crop resulting from the proposed use.

Residue data reflecting application of temephos to citrus, the only currently registered food use for temephos, have been submitted to the Agency (Manuel and Devine, 1970, MRID #000001402). Temephos formulated as Biothion® 6E or as Biothion® 50-WP was applied to oranges, lemons, and grapefruit at sites in Arizona and California. The formulations were applied by airplane or ground equipment following petal fall at 1 or 2 pounds of temephos per acre. Whole fruit was analyzed during maturation, and peel and pulp were analyzed separately at harvest for residues of temephos and temephos sulfoxide. The GLC method of

Pasarela and Orloski (1973, MRID #005000638) was used for residue analysis.

Of 22 samples of immature fruit, seven samples contained detectable (0.05 ppm) temephos up to 0.22 ppm. Three of the samples contained detectable (0.05 ppm) temephos sulfoxide up to 0.08 ppm.

Levels of temephos and temephos sulfoxide in 44 samples of peel and pulp obtained at harvest did not exceed the method sensitivity (0.05 ppm) with one exception: a sample of peel from lemons treated at 2 pounds per acre contained 0.14 ppm temephos and 0.1 ppm sulfoxide (Manuel and Devine, 1970, MRID #000001402). Data on residues in dried citrus pulp or molasses have not been submitted. Also, there are no data on residues in cover crops growing in temephos-treated orchards.

F. Storage/Stability

None of the residue studies has been accompanied by information on sample storage between harvest and analysis. A published study indicates that temephos in fish is partially oxidized to temephos sulfoxide after several weeks of storage in formalin, but is not altered after three weeks of storage at -20°C (Miles *et al.*, 1976, MRID #005000795). The Agency requests that registrants indicate their method of sample storage, and establish that the temephos residue profile is not altered during sample storage.

G. Residues of Temephos in Animals

When use of a pesticide on agricultural crops results in residues in items of animal feed, or when a pesticide is directly applied to animals used for food, the Agency requires data on whether residues are transferred to meat, milk, poultry and eggs.

In one feeding study (Orloski, 1969, MRID #000001392), calves in groups of three were fed, via capsule, equal amounts of temephos and temephos sulfoxide at 0, 0.05, 0.15, and 0.5 ppm each in the diet. After 21 consecutive days of treatment, the animals were slaughtered and residues in muscle, liver, kidney, and fat analyzed by the GLC method of Pasarela and Orloski (1973, MRID #005000638). Temephos or the sulfoxide were not detected in any sample.

In another study (American Cyanamid Co., 1971, MRID #000001403), cows were administered temephos in the diet at 0.3, 0.5, 1.0, 2, 5, 10, 15, and 20 ppm per day. Another cow was fed temephos sulfoxide at 5 ppm per day. Treatment lasted 12 days and milk was sampled during the treatment period and up to 34 days after treatment ceased. Samples were analyzed by the Pasarela and Orloski method (1973, MRID #005000638). Temephos sulfoxide levels did not exceed the method sensitivity (0.01 ppm claimed for milk) except in the cow fed 5 ppm sulfoxide (maximum residue was 0.04 ppm) and a cow fed 20 ppm temephos (0.16 ppm

residue was 0.04 ppm) and a cow fed 20 ppm temephos (0.16 ppm

maximum). Residues of temephos did not exceed 0.02 ppm in cows fed up to 0.5 ppm temephos; maximum residue in cows fed 5 and 20 ppm were 0.22 and 2.23 ppm, respectively. The cow fed the sulfoxide contained more temephos (0.18 ppm maximum) than sulfoxide (0.04 maximum). Temephos residues 34 days after cessation of treatment exceeded 0.01 ppm only in the cow fed 20 ppm of the pesticide (0.09 ppm).

Manuel (1975, MRID #000001344) sprayed Holstein steers to the point of runoff with 0.1% temephos emulsifiable concentrate. At 7, 14, 28, 42 and 56 days after treatment, animals in groups of three were slaughtered, and residues in muscle, liver, kidney, and fat were determined by the method of Pasarela and Orloski (1973, MRID #005000638). Temephos was not detected (<0.05 ppm) in any sample of muscle or liver, but was detected (0.13 and 0.08 ppm) in kidney of two of the three animals slaughtered seven days after treatment. Temephos averaged 1.19 ppm in the fat of the three animals killed at 7 days, and declined thereafter with a half-life of 6 days. The sulfoxide was not detected in muscle, liver, or kidney, but averaged 0.39 and 0.09 ppm in the fat of steers killed 7 and 14 days after treatment, respectively.

Chiu and Eisner (1975, MRID #000001343) sprayed three lactating goats with a ^{14}C-temephos formulation at a rate of 10 mg/kg and a fourth goat was sprayed with a non-radioactive formulation. Milk was collected daily during the study, and animals were sacrificed 2, 7, 14 days after treatment. Milk and tissues were analyzed for total radioactivity and results of the study are tabulated in Table VII.D.

H. Summary of Data Gaps

The data gaps for temephos regarding residue chemistry are:

1) data on the metabolism of temephos in citrus*. As a result of the required metabolism studies, if metabolites other than temephos sulfoxide are found to be present in toxicologically significant amounts then the following second tier tests are needed:

a) an analytical method, or methods, for the determination of the newly identified metabolites, and

b) data on residues of the metabolities in mature citrus and in citrus by-products (if finite residues in mature citrus are found).

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* As an alternative to data from citrus, registrants may submit data demonstrating that metabolism of temephos in a variety of food crops is similar.

2) data on conditions of sample storage between harvest and analysis, and

3) data on residues in cover crops in temephos-treated* citrus orchards.

Registrants of new food use formulations or new uses for currently registered food use formulations must fill applicable data gaps and must provide residue data, including control values and recovery data, reflecting proposed uses.

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* In lieu of acquiring this residue data, a restriction against grazing or feeding of livestock on temephos-treated cover crops may be imposed.

VIII. Ecological Effects

A. Ecological Effects Profile

1. Technical Temephos

Most algal growth was unaffected with 100 ppb temephos in solution even though the photosynthetic process was affected at very low levels (2-58 ppb; Derby and Ruber, 1971, MRID #000001335). Nitrogen fixation in blue-green algae was unaffected at 500 ppb (Wurtsbaugh and Apperson, 1978, MRID #005000807). Two species of Spartina were unaffected with 1 oz of temephos per acre (3 applications over 3 months) [Busch, 1975, MRID #005001001].

Laboratory studies for temephos show high acute toxicity to birds. LD_{50} values for the most representative avian species are in the neighborhood of 30 to 80 mg/kg (Tucker and Haegele, 1971, MRID #005000975 and Tucker and Crabtree, 1970, MRID #GS0006004). These studies, however, are not considered sufficient to meet guideline requirements and additional data are needed on dose response, age of test species and specific LD_{50} values. Comparative subacute dietary toxicity studies show that avian dietary LC_{50} values range from <30 to 76 ppm for passerines (bluejay, sparrow, cardinal) [Hill, 1971, MRID #000001384]; 92 to 260 ppm for upland game birds (bobwhite, quail, ringneck) [Hill et al., 1975, MRID #000002923]; and up to 894 ppm for waterfowl (mallard) [Hill et al., 1975, MRID #000022923].

The 96-hour LC_{50} values for stripped bass and rainbow trout were shown to be 1.0 and 3.49 ppm, respectively (Korn and Earnest, 1974, MRID #005000819 and Fish Pesticide Research Lab., 1971, MRID #GS0006006, respectively). Bluegill sunfish had a 96-hour LC_{50} of 21.8 ppm (Fish Pesticide Reseach Lab., 1964, 1965, 1970, MRID #GS0006005).

There is sufficient information to characterize the toxicity of temephos as moderately toxic to certain estuarine and marine organisms. The 24-hour LC_{50} and EC_{50} (impairment of predator escape response) values for the fiddler crab are 9.12 ppm and 4.31 ppm, respectively (Ward and Busch, 1976, MRID #005000957). The studies provide supplemental information* and the uses of temephos indicate the need for estuarine or marine testing in order to complete a hazard evaluation.

With acute 96-hour LC_{50} values of 0.01 to 0.082 ppm, temephos is highly toxic to freshwater aquatic invertebrates (Fish Pesticide Research Lab., 1964, 1965, 1970, MRID GS0006005).

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* Studies were not conducted on appropriate test species, see proposed guidelines Section 163.72-3.

Field and artifical stream studies (% ai unknown) indicated that temephos is likely to cause, albeit only temporarily, toxic effects to freshwater aquatic invertebrates in the field. The impact was less severe with sequential or partial application of temephos (Ali and Mulla, 1978, MRID #005000841; Thayer and Ruber, 1976, MRID #005000947; and Ruber and Kocor, 1976, MRID #005000946).

2. Formulations

a. Granular

A 5% granular formulation of temephos was demonstrated to be highly toxic to freshwater aquatic invertebrates (McCann and Pitcher, 1975, MRID #GS0006007). McCann and Pitcher (1975, MRID #GS0006007) determined that the 48-hour LC_{50} to daphnia was 0.54 ppm in one test and 2.5 ppm in another. Field tests using 2% granular temephos at 0.1 lb ai/acre showed that temephos is likely to cause toxic effects to some estuarine and marine organisms (Ward _et al_., 1976, MRID #005001768). The uses of temephos indicate the need for estuarine or marine testing in order to complete a hazard evaluation.

b. Emulsifiable Concentrate

A 43% emulsifiable concentrate was tested on rainbow trout (Kennedy, 1970, MRID #000001337) and bluegill sunfish (Fish Pesticide Research Lab., 1964, 1965, 1970, MRID #GS0006005) and was shown to be of high acute toxicity to fish. The 96-hour LC_{50} for the rainbow trout (Kennedy, 1970, MRID #000001337) was 0.158 ppm and 1.14 ppm for the bluegill sunfish (Fish Pesticide Research Lab., 1964, 1965, 1970, MRID #GS0006005). It has been noted that the 4E formulation is approximately twenty times more toxic to fish that the technical.

Emulsifiable concentrate temephos (4 lbs/gal) is of low to moderate toxicity to bees (Johansen and Eves, 1965, MRID #000001361; Johansen, 1966, MRID #000001358; and Johansen, 1972, MRID #005000837). However, laboratory and field studies using various formulations showed that temephos is toxic to a number of nontarget freshwater aquatic insects (Roberts and Miller, 1970, MRID #005000774; Muirhead-Thomson, 1978, MRID #005000797; Helson and West, 1978, MRID #005000828; Muirhead-Thomson, 1978, MRID #005000798; and Wallace _et al_., 1973, MRID #005000821).

There is also sufficient information to characterize the 5% EC temephos as moderately toxic to certain reptiles and amphibians; however this formulation is not currently registered. The 24-hour LC_{50} (5% EC) for a frog and salamander was 4.18 ppm and 3.97 ppm, respectively (Hatorri, 1974, MRID #005003886).

B. Hazard Assessment

Due to the absence of appropriate environmental fate data and essential nontarget toxicity data, an Ecological Effects Hazard

Assessment cannot be made for manufacturing-use or end-use products of temephos. Preliminary data indicate that the end-use emulsifiable concentrate and the granular products when applied according to directions for aquatic uses as a mosquito larvicide may exceed the Restricted Use criteria [see FIFRA Section 162.11 (c)(2)(iii)(C)]*. However, the Agency cannot propose finalized classification of these products for all intended use sites until the Agency receives and reviews the requested data in Table III.A-5 in Part III.

C. Summary of Data Gaps

The data gaps for technical grade of active ingredient in temephos products are the Avian Single Dose Oral LD_{50} on one waterfowl (preferably the mallard) or on an upland game bird (preferably the bobwhite quail or the ring-necked pheasant); the 96-hour LC_{50} for shrimp, crab and an estuarine or marine fish, and the 48-hour LC_{50} for oyster embryo-larvae or the 96-hour EC_{50} shell deposition data for a representative mollusc; seed germination/seedling emergence and vegetative vigor (Tier I); and growth and reproduction of aquatic plants (Tier I).

The data gaps for the end-use temephos products (emulsifiable concentrate and granular formulations) are: the 96-hour LC_{50} for shrimp, crab and an estuarine or marine fish, and the 48-hour LC_{50} for oyster embryo-larvae or the 96-hour EC_{50} shell deposition data for a representative mollusc (both formulations); acute toxicity to aquatic invertebrates (emulsifiable concentrate only); and fish acute LC_{50} (granular only).

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* The maximum calculated concentration (0.036 to 0.073 ppm) immediately following direct application to a 6-inch layer of water is greater than one tenth (0.0158 ppm) the acute LC_{50} (0.158 ppm) for aquatic organisms as represented by rainbow trout.

IX. Efficacy

A. Efficacy Profile

The review of temephos data and the identification of data gaps are limited to efficacy data only as it related to public health applications. In all other instances the Agency has provided for the waiver of efficacy data submission as a part of the registration process (44 FR 27932, May 11, 1979).

B. Factors Influencing Efficacy

Several factors appear to impact the efficacy of temephos. The relative susceptibility of the target species is one of the more important factors. Other factors are achieving and maintaining a toxic concentration of the active ingredient at the treatment site for a sufficient period of time to reach the required level of control.

Factors which influence achieving and maintaining a toxic concentration of the active ingredient at the treatment site are: 1) the rate of release of active ingredient (impacting on how fast the toxic concentration is achieved) and how long the toxic level is maintained (as indicated by Bender, 1964, MRID #000001245; Wall and Marganian, 1971, MRID #005000928; Mulla and Chaudhury, 1968, MRID #005000750; American Cyanamid Co., 197?, MRID #000001260; and American Cyanamid Co., 1976, MRID #000001272) and 2) the organic content and/or pollution level of the water at the treatment site (Bender, 1965, MRID #000001398 and Hagmann, 1966, MRID #005000637).

C. Use Sites

1. Non-Agricultural Aquatic Sites

The test data reviewed by the Agency clearly indicates that temephos granular products containingl, 2 or 5% active ingredient are efficacious for use as a mosquito and biting midge larvicide. The data supports the mosquito larviciding at differential rates, these range from a low rate for temporary rainpools to the high rate for highly polluted waters. Also, effective control of biting midge larvae has been demonstrated in intertidal zones of sandy beaches and marshlands.

The data also support the use of emulsifiable concentrate products containing 4 lbs active ingredient per gallon for control of mosquito larvae. The low rates are for aquatic areas of clean open water and the high rates are for aquatic areas high in organic matter. No claims are made for utilizing emulsifiable concentrate products in highly polluted waters.

Both the emulsifiable concentrate and granular products were applied by air and ground equipment. The efficacy of these products are independent of the method of application.

2. Pets and Pet Living Quarters

The data clearly indicate that direct application of products containing 2% active ingredient and pet collars containing 40.7% active ingredient are efficacious for control of fleas on cats and dogs.

No data have been submitted for evaluating temephos dust for control of fleas in pet-living quarters. However, the studies on pet flea control shows that temephos dust is effective against fleas. Consequently, dust data will be considered adequate to demonstrate the efficacy of dust against fleas on cats, dogs, and in their living quarters.

3. Target Pests

The names currently used on registered temephos labels are general terms which include many different insect species. For example, the term "gnat" includes many species and groups of innocuous flies which, in the adult stage, create problems because of their large numbers, their attraction to people or animals, and their annoyance to man and animals. The midges (Family: Chironomidae) are included in this group. However, the term "gnats" specifically excludes biting gnats (Family: Simuliidae, the buffalo gnats/black flies and turkey gnats) and biting midges (Family: Ceratopogonidae).

The pest species found on registered temephos labels that fall within the Agency's area of public health concern are as follows: mosquito larvae, punky and sandy fly larvae (biting midges, Family: Ceratopogonidae), and fleas.

a. Mosquito Larve*

The term mosquito includes several hundred insect species comprising the Family Culicidae within the Order Diptera. Laboratory studies using representative North American species have demonstrated that there is essentially no difference to the susceptibility of domestic species of mosquito larvae (Craven, and Steelman, 1968, MRID #005000634; Yap et al., 1968, MRID #005000648; Gahan et al., 1966, MRID #005000711; Jones et al.,1976, MRID #005000739; Pelsue et al., 1972, MRID #005000758; Boike and Rathburn, 1969, MRID #005000920; Mount et al., 1971, MRID #005000930; Boike and Rathburn 1972, MRID #005001115; and McFarland and Pelsue, 1971, MRID #005001767).

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* Appropriate dilution rates [e.g., grams of product (weight) or mls of product (liquid) per square feet] must be provided on labels for spot treatments of areas such as, catch basins, containers of water (e.g., old tires) and other water-filled sunken areas where mosquitoes may breed.

Resistance to temephos and cross resistance to other organophosphate larvicides have been reported. The resistance and cross resistance varies with the locality and the mosquito species (Womeldorf *et al.*, 1970, MRID #005000666; Lewallen and Peters, 1966, MRID #005000710; Sutherland and Evans, 1976, MRID #005000740; Gillies, *et al.*, 1968, MRID #005000749; Womeldorf *et al.*, 1972, MRID #005000757; Georghiou *et al.*, 1975, MRID #005000761; Georghiou *et al.*, 1975, MRID #005000888; and Gillies *et al.*, 1975, MRID #005000994). In areas where phosphate resistant mosquitoes are known to exist, it has been shown that up to 0.05 lb active ingredient per acre of the emulsifiable concentrate may be required to achieve adequate control (Bowman, 1965, MRID #000001236). Therefore, the following statement should appear on all temephos emulsifiable concentrate and granular products: "The higher rate should be used in areas known to have organicphosphate resistant mosquitoes."

b. Biting Midge Larvae (Punky and Sand Fly Larvae)

Few studies are available on the efficaciousness of temephos for the control of biting midges. In field studies effective control of *Culicoides melleus* and *C. hollensis* control was obtained when 2% temephos granules were applied at the rate of 0.2 lb active ingredient per acre. These studies were conducted in the intertidal zones of sandy river banks, sandy beaches and on soft mud of tidal marshlands.

c. Fleas

Temephos, in end-use products as a 2% dust and as a 40.7% impregnated collar, has been demonstrated to be effective in controlling the flea (*Ctenocephalides felis*) on dogs and cats. The available data adequately demonstrate the efficaciousness of temephos against fleas infesting both dogs and cats. The dust data will also be considered adequate to demonstrate the control of fleas in both dog and cat living quarters.

Label claims concerning the duration of activity of impregnated collars are formulation dependent and will be required for each formulation registered.

Effective control has been demonstrated for these pests (refer to Table III.C-3 in Part III for references).

D. Summary of Data Gaps

There are no major data gaps pertaining to efficacy regarding temephos.

X. Confidential Annex

Persons wishing to read the contents of this annex, which contains Confidential Business Information, are requested to contact the United States Environmental Protection Agency for further details.

XI. Bibliography

A. Guide to Use of This Bibliography

1. Content of Bibliography

This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: 1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard; 2) citations examined and judged to be inappropriate for use in developing the standard; and 3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry

The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries

The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an nine-digit identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation.

4. Form of the Entry

In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards for the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

a. Author

Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identificable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date

When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title

This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parenthesis

For studies submitted to us in the past, the trailing parenthesis include (in addition to any self-explanatory text) the following elements describing the earliest known submission.

1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example,

within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th 123456-AA.

TEMOPHOS BIBLIOGRAPHY

Section 1

Citations Considered To Be Part Of The Data Base Supporting Registration Under The Standard

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

Product Chemistry (Part IV)

MRID	Citation
000003264	American Cyanamid Company (19??) Chemical and Physical Properties of Abate. (Unpublished study received Feb 7, 1967 under 7G0566; CDL:092854-G)
000003268	American Cyanamid Company (19??) Chemical and Physical Properties of Biothion Insecticide. (Unpublished study received Apr 7, 1971 under 1F1156; CDL:093476-E)
000001254	American Cyanamid Company (1969) Modern Mosquito Control with Abate® Mosquito Larvicide and Insecticide and Cythion® Insecticide, the Premium Grade Malathion. (Unpublished study received 1969 under unknown admin. no.; CDL:128976-A)
000001379	American Cyanamid Company (1972?) [Chemical and Physical Properties of Abate Manufacturing Concentrate Insecticide and Formulations]. (Unpublished study received Jan 12, 1972 under 2270-554; CDL:025308-A)
000001222	American Cyanamid Company (1974?) Stability of Temephos Powder. (Unpublished study received Mar 6, 1974 under 241-234; CDL: 026901-M)
000001223	American Cyanamid Company (1974?) Stability of 25% Temephos Powder Concentrate. (Unpublished study received Mar 6, 1974 under 241-234; CDL:026901-N)
000001216	American Cyanamid Company (1974) Description of Processing Procedure: [Temephos]. (Unpublished study received Mar 6, 1974 under 241-234; CDL:026901-D)
000001278	American Cyanamid Company (1975?) The Specification for Raw Materials used in the Manufacture of Abate®. (Unpublished study received Nov 19, 1975 under 241-246; CDL:224604-C)
000001267	American Cyanamid Company (1976) Manufacturing Procedure for 40.7% Temephos Flea Collar. (Unpublished study received Feb 10, 1976 under 241-251; CDL:229333-H)
GS0006001	American Cyanamid Company (1978) Abate Technical Insecticide. (Letter from J. Robt Gray to Marilyn Mautz, Registration Division, EPA under 241-220; submitted by American Cyanamid Co., Princeton, N.J.)

Product Chemistry (Part IV) (Cont'd)

MRID	Citation
000001269	Fiala, R. (1975) Analytical Method for Temephos Collars. Method M-656 dated Dec 17, 1975. (Unpublished study received Feb 10, 1976 under 241-251; submitted by American Cyanamid Co., Princeton, N.J.; CDL:229333-J)
005000638	Pasarela, N.R.; Orloski, E.J. (1973) Abate insecticide. Pages 119-146, In Analytical Methods for Pesticides and Plant Growth Regulators. Edited by G. Zweig. Vol. VII. Thin-layer and Liquid Chromatography. Pesticides of International Importance. Edited by J. Sherma and G. Zweig. New York: Academic Press.

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Environmental Fate (Part V)

MRID	Citation
005000796	Daorai, A.; Menzer, R.E. (1977) Behavior of Abate in microorganisms isolated from polluted water. Archives of Environmental Contamination and Toxicology 5(2):229-240.
005000718	Drevenkar, V.; Fink, K.; Kovac, V.; Radic, B.; Vasilic, Z. (1977) The fate of pesticides in aquatic environment. III. Thin-layer chromatographic method for the determination of Abate. Arhiv za Higijenu Rada Toksikologiju 28(2):163-169.
005000794	Henry, R.A.; Schmit, J.A.; Dieckman, J.F.; Murphey, F.J. (1971) Combined high speed liquid chromatography and bioassy for the evaluation and analysis of an organophosphorus larvicide. Analytical Chemistry 43(8):1053-1057.
005001102	Steelman, C.D.; Colmer, A.R.; Cabes, L.; Barr, H.T.; Tower, B.A. (1967) Relative toxicity of selected insecticides to bacterial populations in waste disposal lagoons. Journal of Economic Entomology 60(2):467-468.
005003734	Tevan, L.; Lang, F. (1975) Az Abate szunyoglarvairtoszer hatasa a vizi oekoszisztemara. [Effect of Abate, a mosquito larva insecticide, on the ecosystem of water.] Egeszsegtudomany.
005000978	Tsai, S. (1978) Control of chironomids in milkfish (*Chanos*) Transactions of American Fisheries Society 107(3):493-499.
005003887	Vrochinskii, K.K. (1976) Model'naya vodnaya ekosistema kak test opredeleniya opasnosti pestitsida dlya vodoema. [Model of an aquatic ecosystem as a test for determining the extent to which a pesticide is harmful to a water body.] Izvestiya Gosudarstvennogo Nauchno-Issledovatel'skogo Instituta Ozernogo i Rechnogo Rybnogo Khozyaistva. [Bulletin of the State Scientific Research Institute of Lake and River Fisheries.] 109:88-93.
005011182	Wurtsbaugh, W.A.; Apperson, C.S. (1978) Effects of mosquito control insecticides on nitrogen fixation and growth of blue-green algae in natural plankton associations. Bulletin of Environmental Contamination and Toxicology 19:641-647.

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Toxicology (Part VI)

MRID	Citation
000001252	American Cyanamid Company (1964) Toxicity Data [on] Abate 52,160: Report No. 64-113. (Unpublished study received 1964 under unknown admin. no.; CDL:222026-A)
000001354	American Cyanamid Company (1966?) Toxicity Data: Phosphorothioic Acid, O,O,O',O' Tetramethyl O,O' Thiodi-p-Phenylene Ester (Crystalline) [and Abate Mosquito Larvicide]. (Unpublished study received Feb 3, 1967 under 7G0566; CDL:090712-A)
000001308	American Cyanamid Company (1971) Toxicity Data: Abate 2% Dusting Powder: Report No. A-71-152. (Unpublished study received Sep 1, 1972, under 241-230; CDL:002063-E)
000001353	American Cyanamid Company (1971) Toxicity Data: Biothion 6-E Insecticide: Report A-71-137. (Unpublished study received Sep 9, 1975 under 6G1666; CDL:095075-R)
000001233	American Cyanamid Company (1973) Temephos Toxicity Data: Report No. A-73-141. (Unpublished study received Mar 6, 1974 under 241-234; CDL:026901-X)
000001352	American Cyanamid Company (1974) Toxicity Data: Abate 70% Concentrate (AC2233-107): Report A-74-6. (Unpublished study received Sep 9, 1975 under 6G1666; CDL:095075-Q)
000001376	Blinn, R.C. (1966) Abate® Insecticide: The Metabolic Fate of Phenylene Phosphorothioate in the Rat: Project no. 35-54-3-11-83. (Unpublished study received Feb 7, 1967 under 7G0566; submitted by American Cyanamid Co., Agricultural Div., Princeton, N.J.; CDL:092854-H)
005000858	Blinn, R.C. (1969) Metabolic fate of Abate insecticide in the rat. Journal of Agricultural and Food Chemistry 17(1):118-122.
000001343	Chiu, T.Y.; Eisner, S.K. (1975) Temephos: Metabolism of ^{14}C-Temephos Dermally Sprayed on Lactating Goats: Project no. 2-755. (Unpublished study received Sep 9, 1975 under 6G1666; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 095075-N)
000001312	Cole M.M.; Hirst, J.M.; Gilbert, I.H.; Adams, C.T. (1971) Sleeve tests of insecticides for control of body lice in 1969-70. Journal of Economic Entomology 64(3):761-762. (Also In unpublished submission received Sep 1, 1972 under 241-230; submitted by American Cyanamid Co.; Princeton, N.J.; CDL:002063-K)

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Toxicology (Part VI) (Cont'd)

MRID	Citation
000001307	Fischer, J. (1974) Toxicity Data: Temephos, 25% Dust Concentrate: Report No. A-74-120. (Unpublished study received Oct 21, 1974 under 241-235; CDL:100873-A)
005000974	Gaines, T.B. (1969) Acute toxicity of pesticides. Toxicology and Applied Pharmacology 14(3):515-534.
000001368	Gaines, T.B.; Kimbrough, R.; Laws, E.R., Jr. (1967) Toxicology of Abate in laboratory animals. Archives of Environmental Health 14(?/Feb):283-288. (Also In unpublished submission received Jul 17, 1967 under 7G0566; submitted by American Cyanamid Co., Princeton, N.J.; CDL:090713-I)
000001240	Hutchison, E.B.; Levinskas, G.J. (1965) CL 52,160: Ninety-Day Repeated Feeding to Dogs: Report No. 65-19. Method dated Mar 9, 1965 entitled: Modified Michel Method for Assay of Cholinesterase Activity. (Unpublished study received May 27, 1965 under 241-132; submitted by American Cyanamid Co., Princeton, N.J.; CDL:001791-S)
000001356	Hutchinson, E.B.; McNerney, J.M.; Levinskas, G.J. (1966) Abate (CL 52,160): Report no. 66-162. Undated method entitled: Modified Michel Method for Assay of Cholinesterase Activity. (Unpublished study received Feb 3, 1967 under 7G0566; submitted by American Cyanamid Co., Agricultural Div., Princeton, N.J.; CDL:090712-D)
000001375	Laws, E.R., Jr.; Morales, F.R.; Hayes, W.J., Jr.; Romney Joseph, C. (1967) Toxicology of Abate in volunteers. Archives of Environmental Health 14(?/Feb):289-291. (Also In unpublished submission received Feb 7, 1967 under 7G0566; submitted by American Cyanamid Co., Agricultural Div., Princeton, N.J.; CDL:092854-E)
000001239	Levinskas, G.J. (1965) Report on CL 52,160: Ninety-Day Feeding to Albino Rats: Report No. 65-18. Method dated Mar 9, 1965 entitled: Modified Michel Method for Assay of Cholinesterase Activity. (Unpublished study received May 27, 1965 under 241-132; submitted by American Cyanamid Co., Princeton, N.J.; CDL:001791-R)
000001365	McNerney, J.M.; Levinskas, G.J. (1967) Abate Mosquito Larvicide: Single Oral Dose Toxicity to Rats and Joint Toxic Action with Other Pesticides: Report nos. 67-45 and 67-169. (Unpublished study received Jul 17, 1967 under 7G0566; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090713-B)

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Toxicology (Part VI) (Cont'd)

MRID	Citation
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005000806	Shafik, M.T. (1970) The determination of 4,4'-thiodiphenol in human and rat urine as an indication of exposure to low levels of Abate. Bulletin of Environmental Contamination and Toxicology 5(4):311-316.
005001984	Steinberg, M.; Rowe, S.E.; Boldt, R.E. (1970) Assessment of Relative Toxicity of Candidate Louse Toxicant ENT-27165 O,O,O',O'-Tetramethyl O,O'-Thiodi-P-Phenylene Phosphorothioate (Abate): Evaluation of Animal and Human Exposure Data and Recommendations Concerning a Field Test Program. Edgewood Arsenal, Md.: U.S. Army Environmental Hygiene Agency. (USAEHA study no. 33-001-70; available from: NTIS, Springfield, VA; AD 869 265)
005001274	Steinberg, M.; Godke, R.A.; Miller, T.A. (1970) Human exposure to 2 percent ENT-27165 (O,O,O',O'-tetramethyl O,O'-thiodi-p-phenylene phosphorothioate) Abate in pyrax powder and 2 percent ENT-27041 (4-benzothienyl-N-methylcarbamate) Mobam in pyrax powder evaluations of findings from volunteer use of louse toxicant with recommendation for standardization, January-March, 1970. Edgewood Arsenal, Md.: U.S. Army Environmental Hygiene Agency. (USAEHA Toxicologic and Entomologic special study no. 99-006-70/71: available from: NTIS, Springfield, VA; AD-877 508)
000001386	Underwood, P.C. (1977) Two-Year Chronic Toxicity and Carcinogenesis Study of Temephos in the Rat: Report No. 7354. (Unpublished study received Apr 4, 1978 under 241-220; prepared by Pharmacopathics Research Laboratories, Inc.; submitted by American Cyanamid Co., Princeton, N.J.; CDL:233402-B; 235935)
000001232	Wang, G.T.; Colavita, J.H.; Phillips, A.A. (1974) Temephos: Safety of 2% Temephos Powder When Applied Liberally on Cats Five Days a Week for Three Weeks: Project No. 30-0960-3-755. (Unpublished study received Mar 6, 1974 under 241-234; submitted by American Cyanamid Co., Princeton, N.J.; CDL:026901-W)

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Residue Chemistry (Part VII)

MRID	Citation
000001363	American Cyanamid Company (1966) The Determination of Abate Residues in Cottonseed. Method dated Apr 12, 1966. (Unpublished study received Feb 3, 1967 under 7G0566; CDL:090712-U)
000001403	American Cyanamid Company (1971?) Cattle Feeding Studies: [Abate: Residues in Cattle Tissues and Milk]. Undated method entitled: Determination of Abate in Bovine Muscle, Kidney, and Liver; Undated method entitled: Determination of Abate in Bovine Fat; Method M-126 dated Oct 12, 1970. (Unpublished study received Apr 23, 1971 under 1F1156; CDL:090947-AD)
000001377	Blinn, R.C. (1966) Abate® Insecticide: The Metabolic Fate of O,O,O',O'-Tretramethyl O,O'-Thiodi-p-Phenylene Phosphorothioate on Bean Leaves: Project no. 35--54-3-11-83. (Unpublished study received Feb 7, 1967 under 7G0566; submitted by American Cyanmid Co., Agricultural Div., Princeton, N.J.; CDL:092854-I)
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GS0006003	Gibson, M. (1970) Pesticide Petition No. 6F0913 Method Tryout, Abate on Cottonseed. (Letter from Maxwell Gibson, DHEW, Laboratory Director, to George Beusch, Pesticide Evaluation Branch, Office of Pesticide Products Safety Bureau of Foods, BF-216, on Apr 15, 1970)
000001297	Higham, J.M. (1969) Abate® (CL 52,160) and Abate Sulfoxide (CL 105,103) Residues in Cottonseed: Report No. C-198. Undated method. (Unpublished study received Nov 24, 1969 under 241-223; submitted by American Cyanamid Co., Princeton, N.J.; CDL:026905-B)

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Residue Chemistry (Part VII) (Cont'd)

MRID	Citation
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000001402	Manuel, A.J.; Devine, J. (1970) Biothion 6E: Abate® and Abate Sulfoxide Residues in Citrus (Oranges, Lemons, Grapefruit) from Studies Conducted in California and Arizona: Report No. C-246. Method M-145 dated Dec 15, 1970. (Unpublished study received Apr 23, 1971 under 1F1156; CDL:090947-AS)
005000795	Miles, J.W.; Dale, W.E.; Churchill, F.C. (1976) Storage and analysis of samples of water, fish, and mud from environments contaminated with Abate. Archives of Environmental Contamination and Toxicology 5(1):29-41.
000001392	Orloski, E.J. (1969) Abate® and Abate Sulfoxide Residues in Cattle Tissues: Report no. C-206. Method dated Aug 28, 1969 entitled: Determination of Abate in Bovine Muscle, Kidney and Liver; method dated Aug 28, 1969 entitled: Determination of Abate in Bovine Fat. (Unpublished study including letter dated Aug 28, 1969 from A. Post to Edward J. Orloski and MRI Project no. 5-582-C final report, received May 24, 1970 under 0F0913; prepared in cooperation with Midwest Research Institute, submitted by American Cyanamid Co., Agricultural Div., Princeton, N.J.; CDL:091568-AB)
005000638	Pasarela, N.R.; Orloski, E.J. (1973) Abate insecticide. Pages 119-146, In Analytical Methods for Pesticides and Plant Growth Regulators. Edited by G. Zweig. Vol. VII. Thin-layer and Liquid Chromatography. Pesticides of International Importance. Edited by J. Sherma and G. Zweig. New York: Academic Press.
GS0006002	Zee, K.T. (1971) Method Trail for Abate and Abate Sulfoxide on Cotton Seed (Unpublished study received 1971 under 0F0913)

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Ecological Effects (Part VIII)

MRID	Citation
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005001001	Busch, D.A. (1975) The failure of temephos and chloropyrifos to affect the short-term productivity of Spartina alterniflora and S. patens on a New Jersey salt marsh. Pages 50-55, In Proceedings of the Sixty-second Annual Meeting of the New Jersey Mosquito Contronl Association; Mar 11-14, 1975, Atlantic City, New Jersey. new Brunswick, N.J.: New Jersey Mosquito Extermination Association.
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